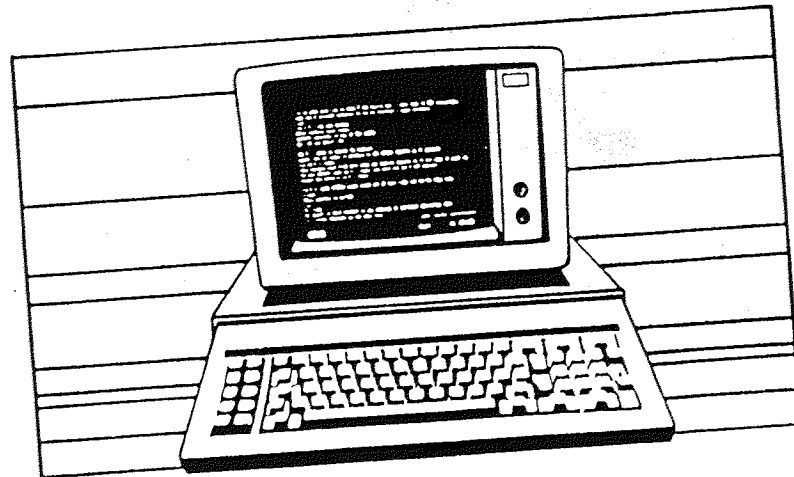


# INACTIVE INGREDIENT GUIDE



**DIVISION OF  
DRUG INFORMATION RESOURCES**

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF MANAGEMENT**

JANUARY 1996

**— OFFICIAL USE ONLY —**

## INACTIVE INGREDIENT GUIDE

**Purpose** The *Inactive Ingredient Guide* contains all inactive ingredients present in approved drug products or conditionally approved drug products currently marketed for human use. The *Guide* is compiled by the Division of Drug Information Resources (DDIR). It provides CDER/CBER Reviewers with information on inactive ingredients in products which have been approved by the Agency. Once an inactive ingredient appears in a currently approved drug product for a particular route of administration, the inactive ingredient would not usually be considered new and may require a less extensive review.

**Design** The *Inactive Ingredient Guide* has been sorted first alphabetically by ingredient, and then by route of administration and dosage form. Routes of administration and dosage forms are derived from current approved labeling.

**Definitions** 21 CFR 210.3(b)(8,7, respectively) defines inactive ingredients and active ingredients as follows: "Inactive ingredient means any component other than the active ingredient. Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. The term (active ingredient) includes those components that may undergo chemical change in the manufacture of the drug product and be present in the finished drug product in a modified form intended to furnish the specified activity or effect." As an exception of the CFR definition, inactive ingredients listed in the *Guide* include only those which are present in the final dosage form of the drug product.

**Synonyms** DDIR maintains a dictionary of all ingredients contained in submissions to CDER. Since many ingredients have synonyms (which do not appear in the *Inactive Ingredient Guide*), it may assist you to contact your Drug Information Officer if you cannot find a particular inactive ingredient.

**Proprietary Inactive Ingredients** DDIR does not always include the components of proprietary inactive ingredients (e.g., OPACODES). In such situations where components of proprietary inactive ingredients are included, you may have to search for such data under individual component entries.

**Warnings** The *Inactive Ingredient Guide* lists inactive ingredients specifically intended as such by the manufacturer. Some of these inactive ingredients could also be considered as active ingredients under different circumstances (see 21 CFR 210.3(b)(7,3)). Furthermore, reactants in radiopharmaceutical kits, or inactive ingredients which physically or chemically combine with active ingredients to facilitate drug transport are considered as inactive ingredients for the purposes of this *Guide*.

[Continued]

**Contaminants** The *Inactive Ingredient Guide* does not represent contaminants found in approved drug products.

**Carcinogens and Teratogens** If any of the inactive ingredients represented in the *Inactive Ingredient Guide* are proven to be carcinogenic, teratogenic, or embryotoxic, please notify DDIR immediately. DDIR will attempt to relay your concern to each medical officer and pharmacologist reviewer responsible for oversight of other approved drug products which contain the specified inactive ingredient.

**CAS Number** Many inactive ingredients have Chemical Abstracts Service (CAS) numbers associated with them. These can be found in the column to the right of the inactive ingredient. CAS numbers may be helpful to CDER/CBER Reviewers when initiating computer-assisted searches with the National Library of Medicine's online data bases.

**Qualitative NDA Data** The next five columns to the right of the CAS number serve to qualify the data presented. The 'NDA CT' reflects the total number of NDAs in which a particular inactive ingredient currently appears. The 'Last NDA' specifies which NDA was the most recent one to be approved by the Agency with this inactive ingredient. The 'APPROVAL DATE' and 'DIV' specify the approval date and Review Division responsible for evaluating this most recent NDA. The 'POTENCY RANGE' specifies the minimum and maximum amounts of inactive ingredients for each route of administration and dosage form. In some cases, values in the 'POTENCY RANGE' column have been collapsed into percentage of the total product in order to integrate data.

**Colors** The Certification Branch of the Division of Color Technology has designated permanently listed, provisionally listed, and delisted color additives. These appear in the Appendix. Please consult the 21 CFR 74 and 82 for detailed information on uses, restrictions, and tolerances of color additives.

**Inactive Ingredient Structures** Chemical structures of all inactive ingredients which have been submitted to the Agency are available for review by contacting Rona Sun or Kyung Kim, DDIR Chemists, at 443-3910.

**Procedure for Obtaining Further Assistance** The Division of Drug Information Resources can also provide you with more specialized searches on the automated data base from which the *Inactive Ingredient Guide* is generated. For assistance in using the *Guide*, to schedule a presentation on the *Guide*, or for a more detailed search, contact your DDIR Drug Information Officer on the following page or Mark Askine at 443-0500.

**DIVISION OF DRUG INFORMATION RESOURCES**  
**DRUG INFORMATION OFFICERS**

Division of Cardio-Renal Drug Products, HFD-110 ..... Diane Centeno-Deshields, R.Ph.  
Division of Neuropharmacological Drug Products, HFD-120 ..... Diane Centeno-Deshields, R.Ph.  
Division of Oncologic Drug Products, HFD-150 ..... Sharon Brownnewell  
Division of Medical Imaging, Surgical, and Dental Products, HFD-160 ..... Herbert Thornton, R.Ph.  
Division of Anesthetic, Critical Care, and Addiction Drug Products, HFD-170 ..... Mary Guilderson  
Division of Gastrointestinal and Coagulation Drug Products, HFD-180 ..... Richard Lipov, R.Ph.  
Division of Metabolism and Endocrine Drug Products, HFD-510 ..... Ronald Brown, R.Ph.  
Division of Anti-Infective Drug Products, HFD-520 ..... Mark W. Askine, R.Ph.  
Division of Antiviral Drug Products, HFD-530 ..... Lee Anne Parsons  
Division of Dermatologic and Ophthalmologic Drug Products, HFD-540 ..... Mark W. Askine, R.Ph.  
Division of Anti-Inflammatory, Analgesic, and Dental Drug Products, HFD-550 ..... Mary Guilderson  
Division of Pulmonary Drug Products, HFD-570 ..... Sharon Brownnewell  
Division of Generic Drugs, HFD-600 ..... Janet Anderson, R.Ph.

All DDIR Drug Information Officers can be contacted at 443-0500 and are located in Room 218 of the Chapman Building.

## INACTIVE INGREDIENT FIELD DESCRIPTION

|  |           |  |
|--|-----------|--|
| <b>INGREDIENT</b><br>ROUTE/DOSAGE FORM   | CAS#      | <b>Ingredient</b> Chemical substance added to enhance formulation of given dosage forms. Component of product other than active ingredient.  |
| <b>ACACIA</b><br>BUCCAL/SUBLINGUAL; TABLET<br>ORAL; CAPSULE<br>ORAL; CAPSULE, SUSTAINED ACTION<br>ORAL; POWDER | 009000015 | <b>Route/Dosage Form</b> Formulation intended for the specified route of administration or site of application.<br><br><b>CAS#</b> Registry number assigned to a compound by Chemical Abstracts Service on a random basis. |

| NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIVISION | POTENCY<br>RANGE |
|--------------|-------------|------------------|----------|------------------|
| 2            | N85125      | 02/02/77         | 600      | 4.0 - 9.1 MG     |
| 1            | N85296      | 04/01/77         | 600      |                  |
| 1            | N17078      | 08/02/76         | 120      | 0.01 - 0.7 MG    |
| 1            | N16640      | 08/03/73         | 510      | 21.0%            |

**NDA Count** Reflects total number of approved NDAs in which a particular inactive ingredient currently appears.

**Last NDA** Specifies which NDA was the most recent one to be approved by the Agency with this active ingredient.

**Approval Date and DIV** Specifies the approval date and the Review Division responsible for evaluating this most recent NDA.

**Potency Range** Specifies the minimum and maximum amounts of inactive ingredients for each route/dosage form.

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| ACACIA   | 009000015 |              |             |                  |     |                  |
| BUCCAL/SUBLINGUAL; TABLET                      |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                  |
| ORAL; POWDER                                   |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 03/08/88         | 600 |                  |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 113          |             | 09/29/95         | 600 | 0.03GM           |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 07/29/92         | 600 | 3.22MG - 80.0MG  |
| ORAL; TABLET, COATED                           |           | 51           |             | 02/25/92         | 600 | 0.02MG - 156.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                      |           | 7            |             | 03/15/83         | 600 | 0.04MG - 0.08MG  |
| ORAL; TABLET, REPEAT ACTION                    |           | 2            |             | 03/31/81         | UNK | 11.542MG         |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 13           |             | 01/04/95         | 600 | 2.0MG - 34.4MG   |
| ORAL-21; TABLET                                |           | 2            |             | 10/01/76         | 510 | 1.26MG           |
| ORAL-28; TABLET                                |           | 4            |             | 03/29/76         | 510 | 1.26MG           |
| ACACIA MUCILAGE                                | 008047389 |              |             |                  |     |                  |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                  |
| ACETIC ACID                                    |           |              |             |                  |     |                  |
| IM - IV - SC; INJECTION                        |           | 1            |             |                  |     |                  |
| IM - SC; INJECTION                             |           | 1            |             |                  |     |                  |
| INTRAMUSCULAR; INJECTION                       |           | 3            |             | 07/09/80         | 510 |                  |
| INTRAVENOUS; INJECTION                         |           | 10           |             | 07/31/90         | 600 | 0.046%           |
| IV(INFUSION); INJECTION                        |           | 9            |             | 03/25/94         | 160 | 0.027% - 0.44%   |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION         |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION                           |           | 1            |             |                  |     |                  |
| SUBCUTANEOUS; INJECTION                        |           | 1            |             |                  |     |                  |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                  |
| TOPICAL; SPONGE                                |           | 1            |             |                  |     |                  |
| ACETIC ACID, GLACIAL                           | 000064197 |              |             |                  |     |                  |
| IM - IV - SC; POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                  |
| IM - IV; INJECTION                             |           | 5            |             | 05/02/88         | 600 | 0.135% - 0.25%   |
| IM - IV; POWDER, FOR INJECTION SOLUTION        |           | 1            |             |                  |     |                  |
| IM - SC; INJECTION                             |           | 7            |             | 04/14/95         | 600 | 0.01% - 0.48%    |
| IM - SC; INJECTION, SUSTAINED ACTION           |           | 1            |             |                  |     |                  |
| INTRA-ARTICULAR; INJECTION                     |           | 3            |             | 05/01/78         | 600 |                  |
| INTRAMUSCULAR; INJECTION                       |           | 9            |             | 05/02/88         | 600 | 0.006% - 0.0442% |
| INTRASYNOVIAL; INJECTION                       |           | 3            |             | 05/07/78         | 600 |                  |
| INTRAVENOUS; INJECTION                         |           | 13           |             | 03/17/94         | UNK | 0.01% - 0.225%   |
| IRRIGATION; SOLUTION                           |           | 1            |             |                  |     |                  |
| IV(INFUSION); INJECTION                        |           | 27           |             | 10/21/95         | 510 | 0.12% - 0.435%   |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                  |
| IV(INFUSION); SOLUTION, INJECTION              |           | 1            |             |                  |     |                  |
| NASAL; SOLUTION                                |           | 1            |             |                  |     |                  |
| NASAL; SPRAY, METERED                          |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION                           |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, HARD GELATIN                    |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| ACETIC ACID, GLACIAL                         | 000064197 | 2            |             | 12/16/85         | 600 | 0.075% - 0.1%   |
| ORAL; CONCENTRATE                            |           | 1            |             |                  |     |                 |
| ORAL; SOLUTION, ELIXIR                       |           | 1            |             |                  |     |                 |
| OTIC; SOLUTION                               |           | 2            |             | 11/06/85         | 600 | 0.36%           |
| OTIC; SUSPENSION                             |           | 2            |             | 06/12/91         | 510 | 0.2%            |
| SUBCUTANEOUS; INJECTION                      |           |              |             |                  |     |                 |
| ACETIC ANHYDRIDE                             | 000108247 | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION               |           |              |             |                  |     |                 |
| ACETONE SODIUM BISULFITE                     | 000540921 | 1            |             |                  |     |                 |
| DENTAL; INJECTION                            |           | 2            |             | 06/30/81         | 600 | 0.4% - 0.50034% |
| INHALATION; SOLUTION                         |           | 3            |             | 11/15/79         | 600 | 0.1% - 0.2%     |
| NERVE BLOCK; INJECTION                       |           |              |             |                  |     |                 |
| ACETYL TRIBUTYL CITRATE                      |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, ENTERIC COATED PELLETS        |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 1            |             |                  |     |                 |
| ORAL; TABLET, ENTERIC COATED PARTICLES       |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION               |           | 2            |             | 01/10/92         | 110 | 2.0MG - 9.0MG   |
| ACETYLATED MONOGLYCERIDES                    |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                       |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 33           |             | 02/21/91         | 600 | 0.04MG - 2.7MG  |
| ORAL; TABLET                                 |           | 2            |             | 04/26/78         | 600 |                 |
| ORAL; TABLET, COATED                         |           | 2            |             | 03/29/82         | 600 | 2.92MG - 5.17MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 10           |             | 02/02/87         | 600 | 0.04MG - 2.1MG  |
| ORAL; TABLET, FILM COATED                    |           | 3            |             | 05/14/85         | UNK |                 |
| ORAL; TABLET, SUSTAINED ACTION               |           |              |             |                  |     |                 |
| ACETYLCYSTEINE                               | 000616911 | 4            |             | 11/22/88         | 600 |                 |
| INHALATION; SOLUTION                         |           |              |             |                  |     |                 |
| ACRYLATES COPOLYMER                          |           | 1            |             |                  |     |                 |
| TRANSDERMAL; FILM, CONTROLLED RELEASE        |           |              |             |                  |     |                 |
| ADCOTE 72A103                                |           | 1            |             |                  |     |                 |
| TRANSDERMAL; FILM, CONTROLLED RELEASE        |           |              |             |                  |     |                 |
| AEROSIL 380                                  |           | 1            |             |                  |     |                 |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           |              |             |                  |     |                 |
| AEROSIL-200                                  |           | 20           |             | 08/17/88         | 600 | 0.1MG - 9.0MG   |
| ORAL; TABLET                                 |           | 2            |             | 02/02/87         | 600 | 3.6MG - 7.2MG   |
| ORAL; TABLET, FILM COATED                    |           |              |             |                  |     |                 |
| AEROTEX RESIN 3730                           |           | 1            |             |                  |     |                 |
| TRANSDERMAL; FILM, CONTROLLED RELEASE        |           |              |             |                  |     |                 |
| AIR  |           | 3            |             | 10/01/82         | 160 |                 |
| INHALATION; GAS                              |           |              |             |                  |     |                 |
| ALBUMIN AGGREGATED                           |           | 5            |             | 12/30/87         | 160 | 0.025%          |
| INTRAVENOUS; INJECTION                       |           |              |             |                  |     |                 |
| ALBUMIN COLLOIDAL                            |           | 1            |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION  |           |              |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| ALBUMIN HUMAN                                | 009006535 | 9            |             | 12/28/90         | 510 | 0.05% - 1.2%       |
| INTRAVENOUS; INJECTION                       |           | 1            |             |                  |     |                    |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION  |           | 1            |             |                  |     |                    |
| IV(INFUSION); INJECTION                      |           | 1            |             |                  |     |                    |
| ALCOHOL                                      | 000064175 | 4            |             | 12/28/95         | 600 | 10.0% - 12.15%     |
| DENTAL; SOLUTION                             |           | 21           |             | 01/29/93         | 600 | 8.55% - 11.0%      |
| IM - IV; INJECTION                           |           | 1            |             |                  |     |                    |
| IM - IV; SOLUTION, INJECTION                 |           | 5            |             | 12/28/84         | UNK | 50.0% - 38.0%      |
| INHALATION; AEROSOL, METERED                 |           | 1            |             |                  |     |                    |
| INHALATION; SOLUTION                         |           | 1            |             |                  |     |                    |
| INTRAMUSCULAR; INJECTION                     |           | 3            |             | 02/10/94         | 600 | 6.8% - 30.5%       |
| INTRAVENOUS; INJECTION                       |           | 1            |             |                  |     |                    |
| IV - SC; INJECTION                           |           | 8            |             | 08/30/95         | 600 | 0.61% - 32.9%      |
| IV(INFUSION); INJECTION                      |           | 2            |             | 12/31/86         | 110 | 10.0% - 30.0%      |
| IV(INFUSION); SOLUTION, INJECTION            |           | 1            |             |                  |     |                    |
| OPHTHALMIC; SOLUTION                         |           | 1            |             |                  |     |                    |
| ORAL; AEROSOL SPRAY                          |           | 13           |             | 08/30/91         | 600 | 0.019% - 71.6%     |
| ORAL; CONCENTRATE                            |           | 28           |             | 11/17/95         | 530 | 0.23% - 30.0%      |
| ORAL; SOLUTION                               |           | 23           |             | 04/29/93         | 600 | 5.0% - 20.4%       |
| ORAL; SOLUTION, ELIXIR                       |           | 18           |             | 09/15/95         | 180 | 0.0000067% - 7.25% |
| ORAL; SUSPENSION                             |           | 35           |             | 10/28/94         | 600 | 0.5% - 7.5%        |
| ORAL; SYRUP                                  |           | 2            |             | 11/17/86         | 600 |                    |
| RECTAL; SUSPENSION                           |           | 1            |             |                  |     |                    |
| TOPICAL; AEROSOL SPRAY                       |           | 2            |             | 06/18/90         | UNK | 52.0%              |
| TOPICAL; GEL                                 |           | 2            |             | 07/03/85         | 600 | 71.0% - 80.5%      |
| TOPICAL; LOTION                              |           | 15           |             | 02/27/95         | 600 | 33.0% - 83.0%      |
| TOPICAL; SOLUTION                            |           | 3            |             | 09/29/95         | 510 |                    |
| TRANSDERMAL; FILM, CONTROLLED RELEASE        |           | 1            |             |                  |     |                    |
| VAGINAL; EMULSION, CREAM                     |           | 7            |             | 10/13/87         | 600 | 0.01% - 10.0%      |
| ALCOHOL, DEHYDRATED                          | 000064175 | 1            |             |                  |     |                    |
| IM - IV; INJECTION                           |           | 1            |             |                  |     |                    |
| IM - IV; POWDER, FOR INJECTION SOLUTION      |           | 4            |             | 04/23/82         | UNK | 1.0% - 34.548%     |
| INHALATION; AEROSOL, METERED                 |           | 2            |             | 11/30/89         | UNK | 10.0%              |
| INTRAMUSCULAR; INJECTION                     |           | 1            |             |                  |     |                    |
| INTRAVASCULAR; INJECTION                     |           | 6            |             | 07/17/95         | 600 | 3.0% - 50.0%       |
| INTRAVENOUS; INJECTION                       |           | 12           |             | 08/30/95         | 600 | 10.0% - 80.0%      |
| IV(INFUSION); INJECTION                      |           | 1            |             |                  |     |                    |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                    |
| IV(INFUSION); SOLUTION, INJECTION            |           | 1            |             |                  |     |                    |
| NASAL; AEROSOL SPRAY                         |           | 1            |             |                  |     |                    |
| NASAL; AEROSOL, METERED                      |           | 2            |             | 10/11/88         | 600 | 0.5%               |
| OPHTHALMIC; SOLUTION                         |           | 5            |             | 11/30/94         | 600 | 0.00003% - 7.37%   |
| ORAL; CONCENTRATE                            |           | 5            |             | 07/14/95         | 530 | 0.1% - 24.9%       |
| ORAL; SOLUTION                               |           | 6            |             | 01/25/82         | 600 | 12.0% - 20.0%      |
| ORAL; SOLUTION, ELIXIR                       |           | 8            |             | 06/18/87         | 600 | 0.26% - 1.0%       |
| ORAL; SUSPENSION                             |           | 19           |             | 11/22/85         | 600 | 5.0% - 7.0%        |
| ORAL; SYRUP                                  |           |              |             |                  |     |                    |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                     | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| ALCOHOL, DEHYDRATED                                 | 000064175 | 4            |             | 01/29/93         | 600 | 20.0% - 94.7808%  |
| TOPICAL; GEL  |           | 5            |             | 09/28/90         | 600 | 55.0% - 77.0%     |
| TOPICAL; SOLUTION                                   |           | 1            |             |                  |     |                   |
| TOPICAL; SWAB                                       |           |              |             |                  |     |                   |
| ALCOHOL, DENATURED                                  | 008024451 | 1            |             |                  |     |                   |
| DENTAL; GEL   |           | 1            |             |                  |     |                   |
| DENTAL; PASTE                                       |           | 1            |             |                  |     |                   |
| TOPICAL; AEROSOL                                    |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, AEROSOL FOAM                     |           | 1            |             |                  |     |                   |
| TOPICAL; GEL  |           | 3            |             | 10/26/84         | UNK | 75.35% - 96.9385% |
| TOPICAL; SOLUTION                                   |           | 5            |             | 01/11/91         | 600 | 44.0% - 60.16%    |
| TOPICAL; SWAB                                       |           | 2            |             | 07/30/93         | 600 | 75.0%             |
| ALCOHOL, DILUTED                                    | 008000166 | 1            |             |                  |     |                   |
| IM - IV; INJECTION                                  |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION                                      |           | 2            |             | 03/16/79         | 600 | 6.5126%           |
| ORAL; SOLUTION, ELIXIR                              |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                                    |           | 3            |             | 08/21/78         | 600 | 0.5% - 1.5%       |
| ORAL; SYRUP   |           | 1            |             |                  |     |                   |
| TOPICAL; AEROSOL SPRAY                              |           | 1            |             |                  |     |                   |
| TOPICAL; POWDER, FOR RECONSTITUTION                 |           | 1            |             |                  |     |                   |
| ALGINIC ACID  | 009005327 | 1            |             |                  |     |                   |
| OPHTHALMIC; DRUG DELIVERY SYSTEM                    |           | 1            |             |                  |     |                   |
| OPHTHALMIC; SUPPOSITORY, INSERT, CONTROLLED RELEASE |           | 2            |             | 05/14/86         | 600 | 17.0MG            |
| ORAL; CAPSULE                                       |           | 22           |             | 12/29/94         | 110 | 0.07MG - 30.0MG   |
| ORAL; TABLET  |           | 3            |             | 06/28/89         | 600 | 150.0MG - 400.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,      |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                                |           | 3            |             | 09/03/80         | 600 | 16.804MG - 52.8MG |
| ORAL; TABLET, FILM COATED                           |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                      |           |              |             |                  |     |                   |
| ALKYL AMMONIUM SULFONIC ACID BETAINE                |           | 1            |             |                  |     |                   |
| TOPICAL; SPONGE                                     |           |              |             |                  |     |                   |
| ALKYL ARYL SODIUM SULFONATE                         |           | 1            |             |                  |     |                   |
| TOPICAL; SUSPENSION, SHAMPOO                        |           |              |             |                  |     |                   |
| ALLANTOIN   | 000097596 | 1            |             |                  |     |                   |
| TOPICAL; GEL  |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM                            |           |              |             |                  |     |                   |
| ALTHEA  |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                                    |           |              |             |                  |     |                   |
| ALUMINUM ACETATE                                    | 000139128 | 1            |             |                  |     |                   |
| OTIC; SOLUTION                                      |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                            |           | 1            |             |                  |     |                   |
| TOPICAL; SHAMPOO                                    |           |              |             |                  |     |                   |
| ALUMINUM HYDROXIDE                                  | 001302290 | 4            |             | 12/22/87         | 600 | 5.0%              |
| TOPICAL; EMULSION, CREAM                            |           | 2            |             | 10/10/85         | 600 |                   |
| TOPICAL; OINTMENT                                   |           |              |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                    | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|--|-----------|--------------|-------------|------------------|-----|----------------|
| ALUMINUM HYDROXIDE - SUCROSE, HYDRATED<br>TOPICAL; EMULSION, CREAM |           | 1            |             |                  |     |                |
| ALUMINUM HYDROXIDE GEL<br>TOPICAL; EMULSION, CREAM                 | 012040594 | 4            |             | 01/29/93         | 600 | 0.3% - 1.0%    |
| ALUMINUM HYDROXIDE GEL F 500<br>TOPICAL; EMULSION, CREAM           |           | 2            |             | 10/08/85         | 600 | 2.0%           |
| ALUMINUM HYDROXIDE GEL F 5000<br>TOPICAL; EMULSION, CREAM          |           | 2            |             | 10/08/85         | 600 | 3.0%           |
| ALUMINUM HYDROXIDE GEL, DRIED<br>ORAL; TABLET                      | 008012633 | 1            |             |                  |     |                |
| ALUMINUM OXIDE<br>ORAL; TABLET                                     | 001344281 | 1            |             |                  |     |                |
| ALUMINUM POLYESTER<br>TRANSDERMAL; FILM, CONTROLLED RELEASE        |           | 1            |             |                  |     |                |
| ALUMINUM POTASSIUM SULFATE<br>VAGINAL; SUPPOSITORY                 |           | 1            |             |                  |     |                |
| ALUMINUM SILICATE<br>ORAL; TABLET                                  | 012141467 | 1            |             |                  |     |                |
| ORAL; TABLET, SUSTAINED ACTION                                     |           | 1            |             |                  |     |                |
| TOPICAL; SUSPENSION, SHAMPOO                                       |           | 1            |             |                  |     |                |
| ALUMINUM STARCH OCTENYLSUCCINATE<br>TOPICAL; EMULSION, CREAM       |           | 1            |             |                  |     |                |
| ALUMINUM STEARATE<br>ORAL; TABLET                                  | 007047849 | 1            |             |                  |     |                |
| ORAL; TABLET, SUSTAINED ACTION                                     |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM   |           | 3            |             | 10/29/93         | UNK |                |
| TOPICAL; OINTMENT  |           | 2            |             | 12/17/90         | UNK |                |
| ALUMINUM SULFATE<br>OTIC; SOLUTION                                 | 010043013 | 2            |             | 02/25/94         | 600 |                |
| TOPICAL; EMULSION, CREAM   |           | 3            |             | 09/28/92         | 600 |                |
| ALZAMER-50<br>ORAL; TABLET, SUSTAINED ACTION                       |           | 1            |             |                  |     |                |
| AMBERLITE<br>ORAL; CAPSULE   | 009002191 | 1            |             |                  |     |                |
| ORAL; TABLET   |           | 9            |             | 12/21/90         | 600 | 1.0MG - 12.0MG |
| ORAL; TABLET, COATED   |           | 1            |             |                  |     |                |
| ORAL; TABLET, FILM COATED  |           | 1            |             |                  |     |                |
| AMERCHOL L101<br>TOPICAL; EMULSION, CREAM                          |           | 5            |             | 08/25/89         | UNK | 1.0% - 5.0%    |
| AMERCHOL-CAB<br>OPHTHALMIC; OINTMENT                               | 008029047 | 2            |             | 12/03/86         | 600 |                |
| AMMONIA<br>INHALATION; LIQUID                                      | 007664417 | 1            |             |                  |     |                |
| AMMONIA SOLUTION<br>ORAL; SUSPENSION                               | 008007576 | 1            |             |                  |     |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| AMMONIUM ACETATE<br>INTRAMUSCULAR; INJECTION                                    | 000631618 | 3            |             | 01/27/95         | 600 | 0.4%               |
| INTRAVENOUS; INJECTION  |           | 3            |             | 01/27/95         | 600 | 0.4%               |
| AMMONIUM CALCIUM ALGINATE<br>ORAL; TABLET                                       |           | 1            |             |                  |     |                    |
| AMMONIUM CHLORIDE<br>ORAL; TABLET   | 012125029 | 6            |             | 06/09/87         | 600 | 2.4MG - 4.2MG      |
| AMMONIUM HYDROXIDE<br>INTRAVENOUS; INJECTION                                    |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE   |           | 4            |             | 05/16/95         | 600 |                    |
| SUBCUTANEOUS; INJECTION   |           | 1            |             |                  |     |                    |
| AMMONIUM PHOSPHATE, DIBASIC<br>ORAL; TABLET                                     | 007783280 | 3            |             | 11/02/87         | 600 | 0.4MG              |
| AMMONIUM SALT OF C-12-C-15 LINEAR PRIMARY ALCOHOL ETHOXYLATE<br>TOPICAL; SPONGE |           | 1            |             |                  |     |                    |
| AMMONIUM SULFATE<br>IM - IV; POWDER, FOR INJECTION SOLUTION                     | 007783202 | 1            |             |                  |     |                    |
| INTRAVENOUS; SUSPENSION, INJECTION  |           | 1            |             |                  |     |                    |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION                                    |           | 1            |             |                  |     |                    |
| AMMONYX<br>TOPICAL; EMULSION, AEROSOL FOAM                                      |           | 1            |             |                  |     |                    |
| TOPICAL; SOLUTION   |           | 1            |             |                  |     |                    |
| TOPICAL; SPONGE   |           | 1            |             |                  |     |                    |
| AMPHOTERIC-2<br>TOPICAL; SUSPENSION, SHAMPOO                                    |           | 1            |             |                  |     |                    |
| AMPHOTERIC-6<br>TOPICAL; EMULSION, CREAM  |           | 1            |             |                  |     |                    |
| ANETHOLE<br>DENTAL; SOLUTION  | 004180238 | 1            |             |                  |     |                    |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                    |
| ORAL; SOLUTION, ELIXIR  |           | 5            |             | 10/03/83         | 600 | 0.003%             |
| ANIDRISORB 85/70<br>ORAL; CAPSULE, SOFT GELATIN                                 |           | 2            |             | 04/20/95         | UNK | 30.045MG - 123.0MG |
| ANISE EXTRACT<br>ORAL; SOLUTION, ELIXIR   | 000104461 | 2            |             | 03/26/76         | 600 |                    |
| ANISE OIL<br>ORAL; PASTILLE   | 008007703 | 1            |             |                  |     |                    |
| ORAL; SOLUTION, ELIXIR  |           | 2            |             | 12/16/83         | 600 |                    |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                    |
| ANISE, STAR<br>ORAL; SOLUTION, ELIXIR   |           | 1            |             |                  |     |                    |
| ANOXID SBN<br>TOPICAL; EMULSION, CREAM  |           | 2            |             | 10/31/94         | 600 | 0.15625%           |
| ANTI-FOAM<br>ORAL; SUSPENSION   | 008051089 | 1            |             |                  |     |                    |
| TOPICAL; LOTION   |           | 2            |             | 07/16/74         | 600 | 0.01% - 0.031%     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| ANTIfoAM DC                                    |           |              |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                 |
| ANTIPYRINE                                     | 000060800 | 1            |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                           |           | 1            |             |                  |     |                 |
| AQUACOAT                                       |           | 1            |             |                  |     |                 |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                 |
| AQUACOAT ECD                                   |           | 2            |             | 10/03/90         | 600 |                 |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                 |
| AQUAPHOR                                       | 008029150 | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                 |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                 |
| ARGININE                                       |           | 3            |             | 03/31/92         | 600 |                 |
| IM - IV; INJECTION                             |           | 1            |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 3            |             | 11/07/95         | 600 | 0.78% - 1.56%   |
| IV(INFUSION); INJECTION                        |           | 1            |             |                  |     |                 |
| ARLATONE 289                                   |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                 |
| ASCORBIC ACID                                  | 000050817 | 1            |             |                  |     |                 |
| CAUDAL BLOCK; INJECTION                        |           | 1            |             |                  |     |                 |
| EPIDURAL; INJECTION                            |           | 1            |             |                  |     |                 |
| IM - IV; INJECTION                             |           | 2            |             | 07/25/74         | 600 | 0.2%            |
| INHALATION; AEROSOL, METERED                   |           | 7            |             | 12/28/84         | UNK | 0.1% - 0.24518% |
| INHALATION; SOLUTION                           |           | 11           |             | 06/13/91         | 600 | 0.02% - 0.038%  |
| INTRAMUSCULAR; INJECTION                       |           | 5            |             | 04/15/88         | 600 | 0.1% - 0.2%     |
| INTRAVENOUS; INJECTION                         |           | 6            |             | 03/09/88         | 600 |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                        |           | 3            |             | 02/16/89         | 600 |                 |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 2            |             | 10/27/83         | 600 |                 |
| NERVE BLOCK; INJECTION                         |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                 |
| ORAL; CONCENTRATE                              |           | 5            |             | 04/27/83         | 600 | 0.05% - 0.2%    |
| ORAL; SUSPENSION, SUSTAINED ACTION             |           | 1            |             |                  |     |                 |
| ORAL; SYRUP                                    |           | 2            |             | 11/15/82         | 600 |                 |
| ORAL; TABLET                                   |           | 6            |             | 08/29/88         | 600 | 1.0MG - 28.44MG |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                 |
| RECTAL; SUPPOSITORY                            |           | 1            |             |                  |     |                 |
| SUBCUTANEOUS; INJECTION                        |           | 1            |             |                  |     |                 |
| ASCORBYL PALMITATE                             | 000137666 | 1            |             |                  |     |                 |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                   |           | 5            |             | 08/14/87         | 600 |                 |
| RECTAL; SUPPOSITORY                            |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                 |
| ASPARTAME                                      | 053906697 | 1            |             |                  |     |                 |
| ORAL; GRANULE, EFFERVESCENT                    |           | 1            |             |                  |     |                 |
| ORAL; POWDER                                   |           | 1            |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 12/23/91         | 520 | 0.16% - 1.05%   |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| ASPARTAME<br>ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,             | 053906697 | 3            |             | 11/16/94         | UNK | 5.41MG - 40.0MG   |
| ASPARTIC ACID<br>IV(INFUSION); INJECTION                                | 000056848 | 2            |             | 02/18/94         | 180 | 0.4% - 0.68%      |
| BALSAM CANADA<br>TOPICAL; LOTION  | 008007474 | 1            |             |                  |     |                   |
| BALSAM, FIR<br>TOPICAL; OIL   |           | 1            |             |                  |     |                   |
| BARIUM SULFATE<br>INTRAUTERINE; SUPPOSITORY, INSERT, CONTROLLED RELEASE | 007727437 | 1            |             |                  |     |                   |
| BEESWAX<br>ORAL; CAPSULE, SOFT GELATIN                                  |           | 2            |             | 11/22/95         | 150 | 7.579MG - 15.16MG |
| ORAL; CAPSULE, SUSTAINED ACTION   |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 16           |             | 09/19/89         | UNK | 0.01MG - 0.1MG    |
| ORAL; TABLET, COATED  |           | 11           |             | 12/20/82         | 600 | 0.02MG - 0.53MG   |
| TOPICAL; EMULSION, CREAM  |           | 4            |             | 06/30/92         | 600 | 1.0%              |
| TOPICAL; OINTMENT   |           | 2            |             | 12/17/90         | UNK | 5.0%              |
| BEESWAX, SYNTHETIC<br>TOPICAL; EMULSION, CREAM                          |           | 1            |             |                  |     |                   |
| BENTONITE<br>ORAL; CAPSULE  | 001302789 | 1            |             |                  |     |                   |
| ORAL; SUSPENSION  |           | 2            |             | 10/17/90         | 600 | 0.45%             |
| ORAL; TABLET  |           | 1            |             |                  |     |                   |
| TOPICAL; SUSPENSION, SHAMPOO  |           | 3            |             | 01/10/91         | 600 | 2.1%              |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                                   |           | 1            |             |                  |     |                   |
| VAGINAL; SUPPOSITORY  |           | 1            |             |                  |     |                   |
| BENZALDEHYDE<br>ORAL; SUSPENSION  | 000100527 | 1            |             |                  |     |                   |
| BENZALKONIUM CHLORIDE<br>INHALATION; SOLUTION                           | 008001545 | 6            |             | 05/28/93         | 600 | 0.01% - 0.025%    |
| INTRA-ARTICULAR; INJECTION  |           | 1            |             |                  |     |                   |
| INTRABURSAL; INJECTION  |           | 1            |             |                  |     |                   |
| INTRADERMAL; INJECTION  |           | 1            |             |                  |     |                   |
| INTRALESIONAL; INJECTION  |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION  |           | 1            |             |                  |     |                   |
| NASAL; SOLUTION   |           | 1            |             |                  |     |                   |
| NASAL; SPRAY  |           | 1            |             |                  |     |                   |
| NASAL; SPRAY, METERED   |           | 10           |             | 10/20/95         | UNK | 0.01% - 0.02%     |
| OPHTHALMIC; GEL   |           | 1            |             |                  |     |                   |
| OPHTHALMIC; OINTMENT  |           | 1            |             |                  |     |                   |
| OPHTHALMIC; SOLUTION  |           | 77           |             | 09/29/95         | 600 | 0.00004% - 10.0%  |
| OPHTHALMIC; SUSPENSION  |           | 28           |             | 09/13/95         | 600 | 0.001% - 0.025%   |
| OTIC; SOLUTION  |           | 4            |             | 01/16/85         | 600 | 0.01% - 0.02%     |
| TOPICAL; LOTION   |           | 2            |             | 03/28/73         | 600 | 0.1%              |
| TOPICAL; SHAMPOO  |           | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION   |           | 2            |             | 04/11/74         | 600 | 0.01%             |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---|-----------|--------------|-------------|------------------|-----|-----------------|
| BENZENESULFONIC ACID SOLUTION<br>INTRAVENOUS; INJECTION |           | 1            |             |                  |     |                 |
| INTRAVENOUS; SOLUTION, INJECTION                        |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                                 |           | 1            |             |                  |     |                 |
| BENZETHONIUM CHLORIDE                                   | 000121540 |              |             |                  |     |                 |
| IM - IV; INJECTION                                      |           | 8            |             | 07/16/81         | 600 | 0.01%           |
| INTRAMUSCULAR; INJECTION                                |           | 1            |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION             |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                                 |           | 1            |             |                  |     |                 |
| NASAL; SPRAY, METERED                                   |           | 1            |             |                  |     |                 |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                  |           | 1            |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                                    |           | 1            |             |                  |     |                 |
| OTIC; SOLUTION  |           | 6            |             | 10/31/94         | 600 | 0.02%           |
| BENZODODECINIUM BROMIDE                                 | 007281041 |              |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                                    |           | 1            |             |                  |     |                 |
| BENZOIC ACID  | 000065850 |              |             |                  |     |                 |
| IM - IV; INJECTION                                      |           | 14           |             | 01/29/93         | 600 | 0.2% - 5.0%     |
| INTRAMUSCULAR; INJECTION                                |           | 1            |             |                  |     |                 |
| IRRIGATION; SOLUTION                                    |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                                 |           | 1            |             |                  |     |                 |
| ORAL; SOLUTION  |           | 8            |             | 04/24/91         | 120 | 0.1%            |
| ORAL; SOLUTION, ELIXIR                                  |           | 4            |             | 10/10/86         | 600 | 0.1%            |
| ORAL; SUSPENSION  |           | 3            |             | 08/28/81         | 110 | 0.1%            |
| ORAL; SYRUP   |           | 8            |             | 01/17/89         | 600 | 0.1%            |
| ORAL; TABLET, COATED                                    |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                                |           | 4            |             | 09/13/95         | UNK | 0.2%            |
| TOPICAL; LOTION   |           | 1            |             |                  |     |                 |
| TOPICAL; SUPPOSITORY                                    |           | 2            |             | 04/26/93         | 520 |                 |
| VAGINAL; EMULSION, CREAM                                |           | 4            |             | 01/04/95         | 600 | 0.1% - 0.2%     |
| VAGINAL; SUPPOSITORY                                    |           | 1            |             |                  |     |                 |
| BENZOIN   | 009000059 |              |             |                  |     |                 |
| ORAL; CAPSULE   |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 1            |             |                  |     |                 |
| BENZYL ALCOHOL  | 000100516 |              |             |                  |     |                 |
| EPIDURAL; INJECTION                                     |           | 1            |             |                  |     |                 |
| IM - IV - SC; INJECTION                                 |           | 9            |             | 12/29/93         | 600 | 0.9% - 1.5%     |
| IM - IV; INJECTION                                      |           | 93           |             | 06/30/94         | 600 | 0.001% - 15.0%  |
| IM - IV; POWDER, FOR INJECTION SOLUTION                 |           | 5            |             | 03/19/82         | 600 | 16.4MG - 66.9MG |
| IM - IV; SOLUTION, INJECTION                            |           | 3            |             | 03/05/90         | 600 | 0.472% - 0.945% |
| IM - SC; INJECTION                                      |           | 15           |             | 07/25/83         | 600 | 0.9% - 2.2%     |
| IM - SC; INJECTION, SUSTAINED ACTION                    |           | 2            |             | 07/14/87         | 600 | 1.2%            |
| INTERSTITIAL; INJECTION                                 |           | 1            |             |                  |     |                 |
| INTRA-ARTERIAL; INJECTION                               |           | 1            |             |                  |     |                 |
| INTRA-ARTICULAR; INJECTION                              |           | 24           |             | 04/09/86         | 600 | 0.001% - 1.0%   |
| INTRABURSAL; INJECTION                                  |           | 5            |             | 02/13/74         | 600 | 0.9%            |
| INTRACAVITARY; INJECTION                                |           | 1            |             |                  |     |                 |
| INTRACAVITARY; POWDER, FOR INJECTION SOLUTION, LYOPHILI |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---|-----------|--------------|-------------|------------------|-----|-----------------|
| BENZYL ALCOHOL                                | 000100516 |              |             |                  |     |                 |
| INTRADERMAL; INJECTION                        |           | 2            |             | 10/16/87         | UNK | 0.9%            |
| INTRALESIONAL; INJECTION                      |           | 8            |             | 10/16/87         | UNK | 0.9% - 1.0%     |
| INTRAMUSCULAR; INJECTION                      |           | 77           |             | 01/27/95         | 600 | 0.001% - 10.45% |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION |           | 2            |             | 02/27/85         | UNK |                 |
| INTRAMUSCULAR; SOLUTION, INJECTION            |           | 1            |             |                  |     |                 |
| INTRAPERITONEAL; INJECTION                    |           | 1            |             |                  |     |                 |
| INTRAPLEURAL; INJECTION                       |           | 1            |             |                  |     |                 |
| INTRASYNOVIAL; INJECTION                      |           | 11           |             | 02/17/84         | 600 | 0.9%            |
| INTRATHECAL; INJECTION                        |           | 2            |             | 05/09/86         | 600 | 0.45% - 0.9%    |
| INTRATUMOR; INJECTION                         |           | 2            |             | 05/09/86         | 600 | 0.45% - 0.9%    |
| INTRAVENOUS; INJECTION                        |           | 60           |             | 07/17/95         | 600 | 0.001% - 3.0%   |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                 |
| INTRAVENOUS; SOLUTION, INJECTION              |           | 4            |             | 12/15/95         | UNK | 0.9% - 2.02%    |
| IV - SC; INJECTION                            |           | 17           |             | 10/10/95         | 600 | 0.9% - 1.5%     |
| IV(INFUSION); INJECTION                       |           | 57           |             | 08/30/95         | 600 | 0.75% - 3.0%    |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION  |           | 5            |             | 07/30/93         | 600 |                 |
| IV(INFUSION); SOLUTION, INJECTION             |           | 1            |             |                  |     |                 |
| NERVE BLOCK; INJECTION                        |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE                                 |           | 36           |             |                  |     |                 |
| ORAL; CAPSULE, SOFT GELATIN                   |           | 1            |             | 12/20/95         | 520 |                 |
| ORAL; CAPSULE, SUSTAINED ACTION               |           | 9            |             |                  |     |                 |
| ORAL; CONCENTRATE                             |           | 1            |             | 08/02/88         | UNK | 1.231MG         |
| ORAL; SOLUTION                                |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                              |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                  |           | 3            |             | 01/05/89         | 110 | 0.49MG - 1.06MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED  |           | 2            |             | 06/19/95         | 520 | 0.94MG - 2.31MG |
| ORAL; TABLET, SUSTAINED ACTION                |           | 1            |             |                  |     |                 |
| SOFT TISSUE; INJECTION                        |           | 4            |             | 05/24/82         | 600 | 0.001% - 0.9%   |
| SUBCONJUNCTIVAL; INJECTION                    |           | 1            |             |                  |     |                 |
| SUBCUTANEOUS; INJECTION                       |           | 4            |             | 02/18/86         | 600 | 0.9%            |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION  |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                      |           | 30           |             | 09/20/95         | UNK | 0.2% - 2.2%     |
| TOPICAL; LOTION                               |           | 9            |             | 12/07/92         | UNK | 0.7% - 1.0%     |
| TOPICAL; OINTMENT                             |           | 3            |             | 10/09/85         | 600 |                 |
| TOPICAL; SOLUTION                             |           | 1            |             |                  |     |                 |
| TOPICAL; SUPPOSITORY                          |           | 1            |             |                  |     |                 |
| URETERAL; SOLUTION                            |           | 1            |             |                  |     |                 |
| VAGINAL; EMULSION, CREAM                      |           | 6            |             | 12/04/95         | 600 | 1.0%            |
| VAGINAL; SUPPOSITORY                          |           | 1            |             |                  |     |                 |
| BENZYL BENZOATE                               | 000120514 |              |             |                  |     |                 |
| INTRAMUSCULAR; INJECTION                      |           | 8            |             | 07/30/81         | 600 | 0.01% - 46.0%   |
| BENZYL CHLORIDE                               | 000100447 |              |             |                  |     |                 |
| INTRAVENOUS; INJECTION                        |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| BETA-NAPHTHOL<br>ORAL; CAPSULE                                | 000135193 | 2            |             | 01/13/76         | 600 |                    |
| BORIC ACID<br>INTRAVENOUS; SOLUTION, INJECTION                | 010043353 | 1            |             |                  |     |                    |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                        |           | 3            |             | 04/02/63         | UNK |                    |
| OPHTHALMIC; SOLUTION  |           | 35           |             | 12/29/95         | 600 | 0.05% - 2.0%       |
| OPHTHALMIC; SUSPENSION  |           | 3            |             | 12/28/82         | 600 | 0.6% - 1.0%        |
| OTIC; SOLUTION  |           | 2            |             | 02/25/94         | 600 |                    |
| TOPICAL; SHAMPOO  |           | 1            |             |                  |     |                    |
| BUFFER, ACETIC ACID-SODIUM ACETATE<br>IM - IV - SC; INJECTION |           | 1            |             |                  |     |                    |
| INTRA-ARTICULAR; INJECTION                                    |           | 1            |             |                  |     |                    |
| INTRAMUSCULAR; INJECTION                                      |           | 2            |             | 11/26/82         | 600 |                    |
| INTRASYNOVIAL; INJECTION                                      |           | 1            |             |                  |     |                    |
| IV(INFUSION); INJECTION                                       |           | 1            |             |                  |     |                    |
| BUFFER, CITRIC ACID-SODIUM CITRATE<br>IM - IV; INJECTION      |           | 1            |             |                  |     |                    |
| IV(INFUSION); INJECTION                                       |           | 1            |             |                  |     |                    |
| SUBCUTANEOUS; SOLUTION, INJECTION                             |           | 1            |             |                  |     |                    |
| BUTANE<br>TOPICAL; AEROSOL SPRAY                              | 000106978 | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, AEROSOL FOAM                               |           | 1            |             |                  |     |                    |
| BUTYL ALCOHOL, TERTIARY<br>TOPICAL; GEL                       | 000075650 | 1            |             |                  |     |                    |
| BUTYLATED HYDROXYANISOLE<br>INTRAMUSCULAR; INJECTION          | 008003245 | 1            |             |                  |     |                    |
| IV(INFUSION); INJECTION                                       |           | 2            |             | 08/08/85         | 510 | 0.0003%            |
| NASAL; SPRAY, METERED   |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE   |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SOFT GELATIN                                   |           | 2            |             | 11/22/95         | 150 | 0.1MG - 0.2MG      |
| ORAL; CONCENTRATE   |           | 1            |             |                  |     |                    |
| ORAL; GRANULE, FOR RECONSTITUTION                             |           | 1            |             |                  |     |                    |
| ORAL; TABLET  |           | 3            |             | 10/31/91         | 600 | 0.04MG - 0.5MG     |
| ORAL; TABLET, FILM COATED                                     |           | 1            |             |                  |     |                    |
| RECTAL; SUPPOSITORY   |           | 4            |             | 08/31/92         | 600 | 0.1025MG - 0.213MG |
| SUBLINGUAL; TABLET  |           | 2            |             | 04/16/81         | 600 | 0.5MG              |
| TOPICAL; EMULSION, CREAM                                      |           | 2            |             | 12/23/82         | UNK | 0.0052%            |
| TOPICAL; OINTMENT   |           | 4            |             | 09/30/83         | UNK | 0.005% - 0.02%     |
| TOPICAL; SUPPOSITORY  |           | 2            |             | 04/26/93         | 520 |                    |
| VAGINAL; EMULSION, CREAM                                      |           | 6            |             | 01/04/95         | 600 | 0.0012% - 0.0044%  |
| VAGINAL; OINTMENT   |           | 1            |             |                  |     |                    |
| VAGINAL; SUPPOSITORY  |           | 2            |             | 04/26/93         | 520 | 1.0MG              |
| BUTYLATED HYDROXYTOLUENE<br>INHALATION; LIQUID                | 000128370 | 1            |             |                  |     |                    |
| INTRAMUSCULAR; INJECTION                                      |           | 1            |             |                  |     |                    |
| IV(INFUSION); INJECTION                                       |           | 2            |             | 08/08/85         | 510 | 0.001%             |
| NASAL; SPRAY, METERED   |           | 1            |             |                  |     |                    |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---------------------------------------|-----------|--------------|-------------|------------------|-----|--------------------|
| BUTYLATED HYDROXYTOLUENE              | 000128370 | 2            |             | 08/17/78         | 510 | 0.016MG - 0.2MG    |
| ORAL; CAPSULE                         |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SOFT GELATIN           |           | 5            |             | 12/11/87         | 600 | 0.1MG - 0.4MG      |
| ORAL; TABLET                          |           | 1            |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION        |           | 4            |             | 08/31/92         | 600 | 0.0125MG - 0.215MG |
| RECTAL; SUPPOSITORY                   |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, AEROSOL FOAM       |           | 4            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM              |           | 7            |             | 11/20/92         | UNK | 0.02% - 0.1%       |
| TOPICAL; GEL                          |           | 2            |             | 10/05/78         | UNK | 0.05%              |
| TOPICAL; OINTMENT                     |           | 2            |             | 06/15/77         | UNK | 0.02%              |
| TOPICAL; SOLUTION                     |           | 2            |             | 05/04/77         | UNK | 0.05%              |
| VAGINAL; EMULSION, CREAM              |           | 1            |             |                  |     |                    |
| VAGINAL; SUPPOSITORY                  |           | 1            |             |                  |     |                    |
| BUTYLENE GLYCOL                       | 000107880 | 1            |             |                  |     |                    |
| TRANSDERMAL; FILM, CONTROLLED RELEASE |           | 1            |             |                  |     |                    |
| BUTYL PARABEN                         | 000094268 | 1            |             |                  |     |                    |
| INTRAMUSCULAR; INJECTION              |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE                         |           | 28           |             | 12/20/95         | 520 |                    |
| ORAL; CAPSULE, SUSTAINED ACTION       |           | 4            |             | 02/14/94         | 600 |                    |
| ORAL; DROPS                           |           | 1            |             |                  |     |                    |
| ORAL; SOLUTION                        |           | 1            |             |                  |     |                    |
| ORAL; SUSPENSION                      |           | 4            |             | 09/25/74         | 520 | 0.0058%            |
| ORAL; SYRUP                           |           | 1            |             |                  |     |                    |
| ORAL; TABLET                          |           | 1            |             |                  |     |                    |
| ORAL; TABLET, COATED                  |           | 3            |             | 09/17/69         | 120 | 0.0028MG - 0.004MG |
| ORAL; TABLET, REPEAT ACTION           |           | 2            |             | 03/31/81         | UNK | 0.006MG            |
| ORAL; TABLET, SUSTAINED ACTION        |           | 5            |             | 11/14/94         | UNK | 0.04MG             |
| RECTAL; SOLUTION                      |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM              |           | 6            |             | 04/27/94         | 600 | 0.2% - 0.4%        |
| TOPICAL; LOTION                       |           | 3            |             | 12/17/81         | 600 | 0.02%              |
| TOPICAL; OINTMENT                     |           | 3            |             | 12/23/83         | 600 | 0.18% - 0.3%       |
| CAFFEINE                              | 000058082 | 1            |             |                  |     |                    |
| OPHTHALMIC; SOLUTION                  |           | 1            |             |                  |     |                    |
| CALCIUM                               | 007440702 | 1            |             |                  |     |                    |
| IM - IV; INJECTION                    |           | 1            |             |                  |     |                    |
| INTRAMUSCULAR; INJECTION              |           | 1            |             |                  |     |                    |
| CALCIUM ACETATE                       | 000062544 | 3            |             | 04/12/88         | 600 | 8.0MG - 8.3MG      |
| ORAL-21; TABLET                       |           | 5            |             | 02/09/89         | 600 | 8.3MG - 10.0MG     |
| ORAL-28; TABLET                       |           | 3            |             | 09/28/92         | 600 |                    |
| TOPICAL; EMULSION, CREAM              |           | 1            |             |                  |     |                    |
| CALCIUM ASCORBATE                     | 005743271 | 1            |             |                  |     |                    |
| ORAL; SUSPENSION                      |           | 1            |             |                  |     |                    |
| CALCIUM CARBONATE, PRECIPITATED       | 000471341 | 2            |             | 12/31/93         | 510 | 125.68MG - 224.7MG |
| ORAL; CAPSULE                         |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, HARD GELATIN           |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION       |           | 1            |             |                  |     |                    |
| ORAL; TABLET                          |           | 32           |             | 04/16/91         | 600 | 4.17MG - 60.0MG    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| CALCIUM CARBONATE, PRECIPITATED                         | 000471341 | 18           |             |                  |     |                   |
| ORAL; TABLET, COATED                                    |           | 1            |             | 02/25/92         | 600 | 0.72MG - 64.8MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED            |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                               |           | 3            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 1            |             | 08/19/91         | UNK | 87.5MG - 229.7MG  |
| ORAL-21; TABLET   |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET   |           | 1            |             |                  |     |                   |
| OTIC; SOLUTION  |           | 2            |             | 02/25/94         | 600 | 0.382%            |
| CALCIUM CHLORIDE  | 010035048 | 1            |             |                  |     |                   |
| CAUDAL BLOCK; INJECTION                                 |           | 3            |             | 12/01/86         | 600 | 0.033%            |
| EPIDURAL; INJECTION                                     |           | 5            |             | 05/02/88         | 600 | 0.004%            |
| IM - IV; INJECTION                                      |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                                |           | 2            |             | 04/28/95         | 600 | 0.048%            |
| INTRAOCULAR; SOLUTION                                   |           | 1            |             |                  |     |                   |
| INTRAPERITONEAL; SOLUTION                               |           | 1            |             |                  |     |                   |
| NERVE BLOCK; INJECTION                                  |           | 6            |             | 12/01/86         | 600 | 0.024% - 0.033%   |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                  |           | 2            |             | 09/22/93         | UNK |                   |
| ORAL; CONCENTRATE                                       |           | 2            |             | 04/27/83         | 600 | 0.008%            |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; INJECTION                                 |           | 1            |             |                  |     |                   |
| CALCIUM GLUCEPTATE                                      | 017140602 | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                  |           | 1            |             |                  |     |                   |
| CALCIUM HYDROXIDE                                       | 001305620 | 1            |             |                  |     |                   |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                                |           | 1            |             |                  |     |                   |
| CALCIUM LACTATE   | 000814802 | 1            |             |                  |     |                   |
| VAGINAL; TABLET   |           | 1            |             |                  |     |                   |
| CALCIUM PHOSPHATE                                       | 010103465 | 1            |             |                  |     |                   |
| ORAL; CAPSULE   |           | 23           |             | 11/18/93         | 110 | 21.5MG - 160.0MG  |
| ORAL; TABLET  |           | 3            |             | 01/15/70         | 510 |                   |
| ORAL; TABLET, COATED                                    |           | 4            |             | 03/15/78         | 120 | 51.5MG - 362.0MG  |
| ORAL; TABLET, FILM COATED                               |           | 1            |             |                  |     |                   |
| ORAL; TABLET, REPEAT ACTION                             |           | 2            |             | 12/30/81         | 510 | 82.9MG - 86.0MG   |
| ORAL-21; TABLET   |           | 2            |             | 12/30/81         | 510 | 86.0MG            |
| ORAL-28; TABLET   |           | 2            |             |                  |     |                   |
| CALCIUM PHOSPHATE DIBASIC DIHYDRATE-SUCROSE AGGLOMERATE |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 1            |             |                  |     |                   |
| CALCIUM PHOSPHATE, DIBASIC                              | 007757939 | 2            |             | 04/10/84         | 600 | 1.8MG - 2.4MG     |
| ORAL; CAPSULE   |           | 2            |             | 04/18/62         | 120 | 5.0MG - 234.04MG  |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 1            |             |                  |     |                   |
| ORAL; PASTILLE  |           | 1            |             |                  |     |                   |
| ORAL; SYRUP   |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 224          |             | 11/30/95         | 600 | 0.031MG - 850.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,          |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                                    |           | 10           |             | 12/20/82         | 600 | 35.0MG - 168.0MG  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED            |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DISPERSIBLE                               |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| CALCIUM PHOSPHATE, DIBASIC                     | 007757939 |              |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                      |           | 4            |             | 12/12/95         | 120 | 101.48MG - 136.25MG |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 2            |             | 08/21/92         | UNK |                     |
| ORAL-21; TABLET                                |           | 2            |             | 04/12/88         | 600 | 40.531MG            |
| ORAL-28; TABLET                                |           | 4            |             | 02/09/89         | 600 | 40.531MG - 104.5MG  |
| TOPICAL; SHAMPOO                               |           | 1            |             |                  |     |                     |
| CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE          | 007789777 |              |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 39           |             | 09/29/95         | 600 | 5.55MG - 378.78MG   |
| ORAL; TABLET, COATED                           |           | 3            |             | 10/03/77         | 600 | 73.3MG - 219.9MG    |
| ORAL; TABLET, FILM COATED                      |           | 3            |             | 12/29/92         | 120 | 26.7MG - 366.3MG    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| CALCIUM PHOSPHATE, TRIBASIC                    | 012167747 |              |             |                  |     |                     |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 9            |             | 11/24/93         | UNK | 9.26MG - 284.0MG    |
| ORAL; TABLET, COATED                           |           | 6            |             | 01/26/84         | 510 | 14.0MG - 21.0MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 3            |             |                  |     |                     |
| ORAL-28; TABLET                                |           | 1            |             | 01/13/81         | UNK | 100.0MG             |
| CALCIUM PYROPHOSPHATE                          | 007790763 |              |             |                  |     |                     |
| ORAL; TABLET                                   |           | 4            |             | 03/22/78         | 600 | 128.52MG - 298.04MG |
| CALCIUM SILICATE                               | 010101390 |              |             |                  |     |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 5            |             | 03/23/87         | 600 | 4.0MG - 15.0MG      |
| CALCIUM STEARATE                               | 001592230 |              |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 16           |             | 12/26/90         | 150 | 0.114MG - 21.1MG    |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 17           |             | 03/16/89         | 600 | 7.93MG - 91.9MG     |
| ORAL; TABLET                                   |           | 83           |             | 09/29/95         | 600 | 0.23MG - 21.0MG     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 4            |             | 06/28/89         | 600 | 15.0MG - 47.5MG     |
| ORAL; TABLET, FILM COATED                      |           | 6            |             | 04/28/95         | 600 | 4.6MG - 10.0MG      |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 5            |             | 10/22/85         | 600 | 10.0MG - 20.0MG     |
| SUBLINGUAL; TABLET                             |           | 2            |             | 02/23/78         | 600 | 2.0MG               |
| CALCIUM SULFATE                                | 007778189 |              |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 3            |             | 10/15/84         | 180 | 50.0MG - 74.68MG    |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 2            |             | 08/02/76         | 120 | 0.53MG - 1.54MG     |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 30           |             | 02/15/89         | 600 | 0.038MG - 307.6MG   |
| ORAL; TABLET, COATED                           |           | 11           |             | 08/16/85         | 120 | 4.532MG - 170.0MG   |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 12/30/83         | 110 | 221.0MG - 443.0MG   |
| ORAL; TABLET, REPEAT ACTION                    |           | 2            |             | 03/31/81         | UNK | 235.0MG             |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 8            |             | 11/14/94         | UNK | 340.0MG             |
| ORAL-28; TABLET                                |           | 3            |             | 11/17/95         | 510 | 10.7MG              |
| CALCIUM SULFATE DIHYDRATE                      | 010101414 |              |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 2            |             | 11/21/74         | 160 | 2.6MG - 370.0MG     |
| ORAL; TABLET                                   |           | 8            |             | 05/24/82         | 600 | 17.45MG - 279.309MG |
| ORAL; TABLET, COATED                           |           | 10           |             | 01/04/82         | 600 | 12.36MG - 214.24MG  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| CALCIUM SULFATE DIHYDRATE<br>ORAL; TABLET, SUSTAINED ACTION    | 010101414 | 1            |             |                  |     |                  |
| CALCIUM SULFATE, ANHYDROUS<br>ORAL; TABLET                     |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED<br>ORAL-28; TABLET                        |           | 2            |             | 01/26/84         | 510 |                  |
| CALDIAMIDE SODIUM<br>INTRAVENOUS; SOLUTION, INJECTION          | 122760912 | 1            |             |                  |     |                  |
| CALTERIDOL CALCIUM<br>INTRAVENOUS; INJECTION                   | 121915831 | 1            |             |                  |     |                  |
| CANDELILLA WAX<br>ORAL; TABLET                                 |           | 6            |             | 11/19/91         | 110 | 0.05MG - 0.316MG |
| ORAL; TABLET, FILM COATED<br>ORAL; TABLET, SUSTAINED ACTION    |           | 1            |             |                  |     |                  |
| CANOLA OIL<br>ORAL; CAPSULE, SOFT GELATIN                      | 008002139 | 2            |             | 05/24/83         | 600 |                  |
| CAPRYLIC/CAPRIC DIGLYCERYL SUCCINATE<br>ORAL; AEROSOL          |           | 1            |             |                  |     |                  |
| CAPRYLIC/CAPRIC TRIGLYCERIDE<br>ORAL; CAPSULE, SOFT GELATIN    |           | 1            |             |                  |     |                  |
| TOPICAL; AEROSOL SPRAY<br>TOPICAL; EMULSION, CREAM             |           | 1            |             |                  |     |                  |
| TOPICAL; SOLUTION  |           | 1            |             |                  |     |                  |
| CARAMEL<br>ORAL; CAPSULE                                       | 008028895 | 1            |             |                  |     |                  |
| ORAL; GRANULE<br>ORAL; POWDER, FOR RECONSTITUTION              |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION<br>ORAL; SYRUP                                  |           | 1            |             |                  |     |                  |
| RECTAL; POWDER, FOR RECONSTITUTION<br>TOPICAL; EMULSION, CREAM |           | 3            |             | 12/03/86         | 600 |                  |
|  |           | 4            |             | 03/02/87         | 600 |                  |
|  |           | 1            |             |                  |     |                  |
| CARBOMER<br>ORAL; TABLET, SUSTAINED ACTION                     |           | 2            |             | 08/12/81         | 600 | 96.0MG           |
| CARBOMER 1342<br>TRANSDERMAL; FILM, CONTROLLED RELEASE         | 009003014 | 1            |             |                  |     |                  |
| CARBOMER 934<br>ORAL; SUSPENSION                               | 009007163 | 2            |             | 08/29/78         | 120 |                  |
| RECTAL; ENEMA<br>TOPICAL; EMULSION, CREAM                      |           | 2            |             | 05/27/94         | 600 |                  |
| TOPICAL; GEL<br>TOPICAL; LOTION                                |           | 4            |             | 06/06/84         | 600 | 0.9%             |
| TOPICAL; OINTMENT<br>TOPICAL; SOLUTION                         |           | 1            |             |                  |     |                  |
|  |           | 12           |             | 09/30/94         | 600 | 0.25% - 0.4%     |
| CARBOMER 934P<br>OPHTHALMIC; SUSPENSION                        |           | 1            |             | 12/15/95         | 600 | 0.15%            |
| ORAL; CAPSULE<br>ORAL; TABLET, SUSTAINED ACTION                |           | 2            |             | 12/30/94         | UNK | 0.2%             |
|  |           | 1            |             |                  |     |                  |
|  |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| CARBOMER 934P                                |           |              |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                     |           | 2            |             | 12/30/92         | UNK | 0.1% - 1.0%     |
| TOPICAL; GEL                                 |           | 3            |             | 04/29/94         | UNK | 0.9% - 1.5%     |
| TOPICAL; LOTION                              |           | 4            |             | 01/31/90         | 600 | 0.3%            |
| TOPICAL; OINTMENT                            |           | 1            |             |                  |     |                 |
| TOPICAL; SOLUTION                            |           | 1            |             |                  |     |                 |
| VAGINAL; GEL                                 |           | 1            |             |                  |     |                 |
| CARBOMER 940                                 | 009007174 |              |             |                  |     |                 |
| OPHTHALMIC; GEL                              |           | 1            |             |                  |     |                 |
| TOPICAL; CREAM, AUGMENTED                    |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                     |           | 4            |             | 06/13/88         | 600 | 0.1% - 0.5%     |
| TOPICAL; GEL                                 |           | 7            |             | 12/30/94         | 600 | 0.6% - 3.5%     |
| TOPICAL; LOTION                              |           | 3            |             | 11/26/85         | 600 | 0.203% - 0.6%   |
| CARBOMER 941                                 | 009003014 |              |             |                  |     |                 |
| TOPICAL; LOTION                              |           | 2            |             | 12/07/92         | UNK | 0.05% - 0.1%    |
| CARBOMER 974                                 | 009003014 |              |             |                  |     |                 |
| ORAL; GRANULE, FOR RECONSTITUTION            |           | 1            |             |                  |     |                 |
| CARBON DIOXIDE                               | 000124389 |              |             |                  |     |                 |
| INHALATION; GAS                              |           | 1            |             |                  |     |                 |
| INTRA-ARTERIAL; SOLUTION, INJECTION          |           | 1            |             |                  |     |                 |
| INTRACARDIAC; INJECTION                      |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; INJECTION                     |           | 1            |             |                  |     |                 |
| INTRATHECAL; INJECTABLE                      |           | 1            |             |                  |     |                 |
| INTRATHECAL; INJECTION                       |           | 1            |             |                  |     |                 |
| INTRAVASCULAR; SOLUTION, INJECTION           |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                       |           | 2            |             | 08/23/78         | 160 |                 |
| INTRAVENOUS; SOLUTION, INJECTION             |           | 1            |             |                  |     |                 |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                 |
| NERVE BLOCK; INJECTION                       |           | 4            |             | 06/21/88         | 600 |                 |
| CARBOXY VINYL COPOLYMER                      |           |              |             |                  |     |                 |
| TOPICAL; GEL                                 |           | 1            |             |                  |     |                 |
| CARBOXYMETHYL STARCH                         | 009057061 |              |             |                  |     |                 |
| ORAL; TABLET                                 |           | 6            |             | 03/25/91         | 600 | 4.75MG - 16.0MG |
| CARBOXYMETHYLAMYLOPECTIN SODIUM              |           |              |             |                  |     |                 |
| ORAL; TABLET                                 |           | 1            |             |                  |     |                 |
| CARBOXYMETHYLCELLULOSE                       | 009000117 |              |             |                  |     |                 |
| INTRA-ARTICULAR; INJECTION                   |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; INJECTION                     |           | 4            |             | 05/24/79         | 520 | 0.1% - 0.9%     |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 2            |             | 04/23/85         | UNK |                 |
| ORAL; DROPS                                  |           | 1            |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION             |           | 2            |             | 12/31/91         | 520 |                 |
| ORAL; SUSPENSION                             |           | 3            |             | 11/17/86         | 600 |                 |
| ORAL; TABLET                                 |           | 4            |             | 02/27/84         | 600 | 2.0MG - 10.8MG  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 1            |             |                  |     |                 |
| RECTAL; SUSPENSION                           |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| CARBOXYMETHYLCELLULOSE CALCIUM                 | 009050048 | 2            |             | 02/21/92         | 520 | 4.0MG - 80.0MG    |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                   |
| CARBOXYMETHYLCELLULOSE SODIUM                  | 009004324 | 1            |             |                  |     |                   |
| DENTAL; GEL                                    |           | 1            |             |                  |     |                   |
| DENTAL; PASTE                                  |           | 4            |             | 07/06/87         | 600 | 0.3% - 16.7%      |
| INTRA-ARTICULAR; INJECTION                     |           | 13           |             | 05/24/82         | 600 | 0.1% - 0.75%      |
| INTRABURSAL; INJECTION                         |           | 5            |             | 02/13/74         | 600 | 0.1% - 0.75%      |
| INTRADERMAL; INJECTION                         |           | 2            |             | 10/16/87         | UNK | 0.75%             |
| INTRALESIONAL; INJECTION                       |           | 3            |             | 10/16/87         | UNK | 0.5% - 0.75%      |
| INTRAMUSCULAR; INJECTION                       |           | 18           |             | 07/07/83         | 600 | 0.1% - 0.75%      |
| INTRASYNOVIAL; INJECTION                       |           | 5            |             | 11/05/81         | 600 | 0.1% - 0.75%      |
| NASAL; SPRAY, METERED                          |           | 3            |             | 10/19/94         | UNK | 1.5%              |
| ORAL; CAPSULE                                  |           | 12           |             | 10/18/95         | 600 | 0.068MG - 160.0MG |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                   |
| ORAL; GRANULE                                  |           | 5            |             | 06/15/88         | 600 |                   |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 17           |             | 04/28/95         | 600 | 0.066% - 0.525%   |
| ORAL; SOLUTION                                 |           | 6            |             | 07/10/95         | 600 | 0.2% - 3.5%       |
| ORAL; SUSPENSION                               |           | 26           |             | 09/15/95         | 180 | 0.13% - 1.2%      |
| ORAL; SYRUP                                    |           | 10           |             | 02/03/86         | 600 | 0.265% - 2.65%    |
| ORAL; TABLET                                   |           | 14           |             | 05/31/94         | 530 | 0.57MG - 41.8MG   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 07/05/88         | 520 | 24.75MG           |
| ORAL; TABLET, COATED                           |           | 4            |             | 05/19/81         | 600 | 2.2MG             |
| SOFT TISSUE; INJECTION                         |           | 2            |             | 05/24/82         | 600 | 0.1% - 0.5%       |
| SUBCUTANEOUS; INJECTION                        |           | 1            |             |                  |     |                   |
| TOPICAL; GEL, JELLY                            |           | 1            |             |                  |     |                   |
| TOPICAL; PASTE                                 |           | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                   |
| CARBOXYPOLYMETHYLENE                           | 009007209 | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                   |
| RECTAL; ENEMA                                  |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                   |
| CARDAMOM                                       |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                   |
| CARMINE  | 008022933 | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, UNCOATED, TROCHE                 |           | 1            |             |                  |     |                   |
| CARMINE SOLUTION                               | 008001807 | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                   |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                   |
| CARMINIC ACID                                  | 000476391 | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| CARNAUBA WAX                                 | 008015869 |              |             |                  |     |                   |
| ORAL; CAPLET                                 |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 2            |             | 08/12/88         | 600 | 0.364MG - 0.75MG  |
| ORAL; TABLET                                 |           | 121          |             | 10/06/95         | UNK |                   |
| ORAL; TABLET, COATED                         |           | 46           |             | 05/17/94         | 600 | 0.02MG - 0.92MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 2            |             | 06/23/81         | 600 |                   |
| ORAL; TABLET, FILM COATED                    |           | 24           |             | 09/29/95         | 600 | 0.01MG - 0.4MG    |
| ORAL; TABLET, REPEAT ACTION                  |           | 2            |             | 03/31/81         | UNK | 0.046MG           |
| ORAL; TABLET, SUSTAINED ACTION               |           | 29           |             | 11/14/94         | UNK | 0.07MG - 200.0MG  |
| ORAL-28; TABLET                              |           | 2            |             | 11/17/95         | 510 | 0.126MG - 0.157MG |
| CARNAUBA YELLOW WAX                          |           |              |             |                  |     |                   |
| ORAL; TABLET, COATED                         |           | 1            |             |                  |     |                   |
| CARRAGEENAN                                  | 009000071 |              |             |                  |     |                   |
| ORAL; GRANULE, FOR RECONSTITUTION            |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION             |           | 2            |             | 11/27/79         | 600 | 0.75%             |
| ORAL; SYRUP                                  |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION                              |           | 2            |             | 12/17/81         | 600 | 0.5%              |
| TRANSDERMAL; FILM, CONTROLLED RELEASE        |           | 1            |             |                  |     |                   |
| CARRAGEENAN SALT                             |           |              |             |                  |     |                   |
| TOPICAL; LOTION                              |           | 1            |             |                  |     |                   |
| CASSIA OIL                                   |           |              |             |                  |     |                   |
| ORAL; SOLUTION, ELIXIR                       |           | 1            |             |                  |     |                   |
| CASTOR OIL                                   | 008001794 |              |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                     |           | 4            |             | 02/28/79         | 600 |                   |
| ORAL; CAPSULE                                |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 4            |             | 02/14/94         | 600 | 1.2MG - 1.756MG   |
| ORAL; GRANULE, FOR RECONSTITUTION            |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                 |           | 5            |             | 03/30/94         | 600 | 0.09MG - 0.15MG   |
| ORAL; TABLET, COATED                         |           | 3            |             | 01/15/70         | 510 | 0.9MG             |
| ORAL; TABLET, FILM COATED                    |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 1            |             |                  |     |                   |
| SUBLINGUAL; TABLET                           |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                     |           | 2            |             | 01/24/80         | UNK | 5.0% - 12.5%      |
| TOPICAL; OINTMENT                            |           | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION                            |           | 1            |             |                  |     |                   |
| CASTOR OIL HYDROGENATED                      | 008001783 |              |             |                  |     |                   |
| ORAL; CAPSULE, SOFT GELATIN                  |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 7            |             | 08/10/92         | 110 | 1.894MG - 13.0MG  |
| ORAL; TABLET                                 |           | 4            |             | 06/25/91         | 110 | 0.5MG - 37.6MG    |
| ORAL; TABLET, COATED                         |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 2            |             | 01/22/87         | 600 | 111.6MG           |
| ORAL-21; TABLET                              |           | 3            |             | 04/12/88         | 600 | 0.8MG             |
| ORAL-28; TABLET                              |           | 5            |             | 02/09/89         | 600 | 0.8MG - 104.5MG   |
| SUBLINGUAL; TABLET                           |           | 1            |             |                  |     |                   |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|---------------------------------|-------|--------------|-------------|------------------|-----|---------------|
| ORAL; CAPSULE, SUSTAINED ACTION |       | 1            |             |                  |     |               |
| ORAL; TABLET                    |       | 1            |             |                  |     |               |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                          | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| CELLULOSE  |           |              |             |                  |     |                  |
| BUCCAL/SUBLINGUAL; TABLET                                |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE  |           | 23           |             | 03/03/95         | 110 | 40.0MG - 405.0MG |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                    |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                          |           | 1            |             |                  |     |                  |
| ORAL; DROPS  |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                         |           | 3            |             | 04/20/88         | 600 |                  |
| ORAL; SUSPENSION   |           | 2            |             | 08/28/81         | 110 | 1.0%             |
| ORAL; TABLET   |           | 54           |             | 06/29/95         | 600 | 0.07GM           |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,           |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                                     |           | 8            |             | 05/19/92         | 110 | 6.7MG - 20.1MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED             |           | 1            |             |                  |     |                  |
| ORAL; TABLET, DISPERSIBLE                                |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                                |           | 9            |             | 08/31/81         | 600 | 5.94MG - 100.0MG |
| ORAL; TABLET, SUSTAINED ACTION                           |           | 4            |             | 09/22/94         | 110 |                  |
| ORAL-21; TABLET  |           | 3            |             | 05/10/82         | 510 | 20.0MG           |
| ORAL-28; TABLET  |           | 4            |             | 11/01/84         | 510 | 20.0MG           |
| SUBLINGUAL; TABLET                                       |           | 1            |             |                  |     |                  |
| CELLULOSE ACETATE  | 009004357 |              |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                           |           | 5            |             | 06/01/94         | 110 | 19.0MG - 23.75MG |
| CELLULOSE ACETATE PHTHALATE                              | 009004380 |              |             |                  |     |                  |
| ORAL; TABLET   |           | 2            |             | 06/22/89         | 600 | 37.0MG           |
| ORAL; TABLET, COATED                                     |           | 1            |             |                  |     |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED             |           | 3            |             | 01/28/88         | UNK | 4.75MG - 24.0MG  |
| ORAL; TABLET, FILM COATED                                |           | 1            |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                           |           | 9            |             | 01/04/95         | 600 | 16.95MG - 70.0MG |
| CELLULOSE MICROCRYSTALLINE/CARBOXYMETHYLCELLULOSE SODIUM |           |              |             |                  |     |                  |
| ORAL; CAPSULE  |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                         |           | 2            |             | 12/23/91         | 520 | 0.5% - 1.3125%   |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |                  |
| ORAL; TABLET   |           | 1            |             |                  |     |                  |
| CELLULOSE MICROCRYSTALLINE, AQUEOUS                      |           |              |             |                  |     |                  |
| ORAL; CAPSULE  |           | 2            |             | 11/19/82         | 600 | 20.0MG           |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |                  |
| ORAL; TABLET   |           | 15           |             | 10/24/92         | UNK | 7.9MG - 240.0MG  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED             |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                                |           | 2            |             | 03/03/95         | UNK | 25.0MG           |
| CELLULOSE, MICROCRYSTALLINE                              | 009004346 |              |             |                  |     |                  |
| INTRAVENOUS; INJECTION                                   |           | 1            |             |                  |     |                  |
| NASAL; SPRAY, METERED                                    |           | 3            |             | 10/19/94         | UNK | 1.5%             |
| ORAL; CAPLET   |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE  |           | 116          |             | 12/20/95         | 520 | 1.5MG - 363.75MG |
| ORAL; CAPSULE, COATED PELLETS                            |           | 2            |             | 10/30/85         | 600 |                  |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                    |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, HARD GELATIN                              |           | 3            |             | 12/06/95         | 550 | 57.22MG - 60.0MG |
| ORAL; CAPSULE, SUSTAINED ACTION                          |           | 6            |             | 09/11/95         | 110 | 20.7MG - 107.0MG |
| ORAL; GRANULE, ENTERIC COATED                            |           | 1            |             |                  |     |                  |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV             | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----------------|-------------------|
| CELLULOSE, MICROCRYSTALLINE                    | 009004346 | 1            |             |                  |                 |                   |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 13           |             | 04/28/95         | 600             | 0.5% - 2.0%       |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 9            |             | 09/15/95         | 180             | 1.2%              |
| ORAL; SUSPENSION                               |           | 1,407        |             | 12/29/95         | 600             | 0.064GM - 0.152GM |
| ORAL; TABLET                                   |           | 6            |             | 09/11/95         | 600             | 42.07MG - 505.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 37           |             | 06/23/95         | 600             | 1.0MG - 107.0MG   |
| ORAL; TABLET, COATED                           |           | 8            |             | 11/30/95         | 600             | 25.0MG - 125.71MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 2            |             | 04/28/95         | 600             |                   |
| ORAL; TABLET, DISPERSIBLE                      |           | 1            |             |                  |                 |                   |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 90           |             | 12/19/95         | 180             | 5.0MG - 160.22MG  |
| ORAL; TABLET, FILM COATED                      |           | 14           |             | 11/18/94         | UNK             | 23.45MG - 226.0MG |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |                 |                   |
| ORAL; TABLET, UNCOATED, TROCHE                 |           | 8            |             | 12/15/95         | 600             | 19.6MG - 20.0MG   |
| ORAL-21; TABLET                                |           | 19           |             | 11/17/95         | 510             | 7.58MG - 20.0MG   |
| ORAL-28; TABLET                                |           | 1            |             |                  |                 |                   |
| RECTAL; SUSPENSION                             |           | 9            |             | 02/26/88         | 600             | 6.0MG - 32.0MG    |
| SUBLINGUAL; TABLET                             |           | 2            |             | 10/17/85         | 600             | 320.0MG - 390.0MG |
| VAGINAL; TABLET                                |           | 5            |             | 10/03/74         | 600             | 0.03GM            |
| CELLULOSE, OXIDIZED                            |           |              |             |                  |                 |                   |
| ORAL; TABLET                                   |           |              |             |                  |                 |                   |
| CELLULOSIC POLYMERS                            |           |              |             |                  |                 |                   |
| ORAL; TABLET                                   |           |              |             |                  |                 |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           |              |             |                  |                 |                   |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           |              |             |                  |                 |                   |
| ORAL; TABLET, FILM COATED                      |           |              |             |                  |                 |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           |              |             |                  |                 |                   |
| CERESIN  | 008001750 | 1            |             |                  |                 |                   |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |                 |                   |
| CETEARETH-12                                   |           |              |             |                  |                 |                   |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |                 |                   |
| CETEARETH-15                                   |           |              |             |                  |                 |                   |
| TOPICAL; EMULSION, AEROSOL FOAM                |           | 1            |             |                  |                 |                   |
| TOPICAL; EMULSION, CREAM                       |           | 7            |             | 01/29/93         | 600             | 1.0% - 7.5%       |
| CETEARETH-20                                   |           |              |             |                  |                 |                   |
| TOPICAL; EMULSION, CREAM                       |           | 11           |             | 12/18/90         | UNK             | 0.75% - 10.0%     |
| TOPICAL; LOTION                                |           | 1            |             |                  |                 |                   |
| TOPICAL; OINTMENT                              | 1         |              |             |                  |                 |                   |
| CETEARETH-30                                   |           |              |             |                  |                 |                   |
| TOPICAL; CREAM, AUGMENTED                      | 1         |              |             |                  |                 |                   |
| TOPICAL; EMULSION, CREAM                       | 3         |              | 07/10/84    | UNK              | 2.25% - 7.2%    |                   |
| CETEARYL ALCOHOL                               |           |              |             |                  |                 |                   |
| ORAL; TABLET, SUSTAINED ACTION                 | 6         |              | 11/08/93    | UNK              | 20.0MG - 40.0MG |                   |
| TOPICAL; EMULSION, CREAM                       | 37        |              | 09/13/95    | UNK              | 1.8% - 11.5%    |                   |
| TOPICAL; LOTION                                | 2         |              | 05/31/89    | UNK              | 2.5% - 3.7%     |                   |
| TOPICAL; OINTMENT                              | 2         |              | 10/10/85    | 600              | 1.2%            |                   |
| TOPICAL; SUPPOSITORY                           | 1         |              |             |                  |                 |                   |
| VAGINAL; EMULSION, CREAM                       | 5         |              | 12/04/95    | 600              | 3.21%           |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|--|-----------|--------------|-------------|------------------|-----|----------------|
| CETEARYL ALCOHOL<br>VAGINAL; SUPPOSITORY       |           | 1            |             |                  |     |                |
| CETEARYL OCTANOATE<br>TOPICAL; EMULSION, CREAM |           | 1            |             |                  |     |                |
| CETETH-10<br>TOPICAL; LOTION                   |           | 1            |             |                  |     |                |
| CETETH-2<br>TOPICAL; EMULSION, CREAM           |           | 1            |             |                  |     |                |
| CETETH-20<br>TOPICAL; EMULSION, CREAM          |           | 13           |             | 06/17/94         | UNK | 0.91% - 4.0%   |
| VAGINAL; TAMPON                                |           | 1            |             |                  |     |                |
| CETYL ALCOHOL                                  | 000124298 |              |             |                  |     |                |
| OPHTHALMIC; SUSPENSION                         |           | 2            |             | 05/11/88         | 600 | 0.5%           |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 5            |             | 01/04/95         | 600 | 0.58MG - 2.0MG |
| OTIC; SUSPENSION                               |           | 3            |             | 09/29/87         | 600 | 0.2% - 1.0%    |
| RECTAL; EMULSION, AEROSOL FOAM                 |           | 1            |             |                  |     |                |
| TOPICAL; AEROSOL                               |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, AEROSOL FOAM                |           | 2            |             | 12/19/79         | 600 | 3.226%         |
| TOPICAL; EMULSION, CREAM                       |           | 77           |             | 06/13/95         | 600 | 0.2% - 10.0%   |
| TOPICAL; LOTION                                |           | 31           |             | 09/30/92         | UNK | 0.0014% - 5.0% |
| TOPICAL; OINTMENT                              |           | 6            |             | 07/24/78         | 600 | 1.5% - 7.0%    |
| VAGINAL; EMULSION, CREAM                       |           | 13           |             | 12/21/95         | 520 | 1.5% - 4.0%    |
| CETYL ESTERS                                   |           |              |             |                  |     |                |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                       |           | 12           |             | 10/26/94         | 600 | 2.0% - 5.0%    |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                |
| TOPICAL; SUPPOSITORY                           |           | 1            |             |                  |     |                |
| VAGINAL; EMULSION, CREAM                       |           | 5            |             | 12/04/95         | 600 |                |
| VAGINAL; SUPPOSITORY                           |           | 1            |             |                  |     |                |
| CETYL PALMITATE                                | 000540103 |              |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                       |           | 4            |             | 09/13/95         | UNK | 0.3144%        |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                |
| VAGINAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                |
| CETYLPYRIDINIUM CHLORIDE                       | 000123035 |              |             |                  |     |                |
| INHALATION; AEROSOL, METERED                   |           | 2            |             | 07/10/62         | UNK |                |
| ORAL; AEROSOL SPRAY                            |           | 1            |             |                  |     |                |
| ORAL; CAPSULE                                  |           | 5            |             | 05/05/94         | 110 | 0.0043MG       |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 6            |             | 01/06/81         | UNK | 0.02MG         |
| CHERRY   |           |              |             |                  |     |                |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                |
| CHERRY JUICE                                   | 008012995 |              |             |                  |     |                |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM        | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV  | POTENCY RANGE  |
|--|-----------|--------------|-------------|------------------|------|----------------|
| CHLOROBUTANOL                          | 000057158 |              |             |                  |      |                |
| IM - IV - SC; INJECTION                |           | 1            |             |                  |      |                |
| IM - IV; INJECTION                     |           | 4            |             | 03/18/75         | 600  | 0.5%           |
| IM - SC; INJECTION                     |           | 2            |             | 06/26/75         | 600  | 0.35% - 0.5%   |
| INHALATION; SOLUTION                   |           | 1            |             |                  |      |                |
| INTRAMUSCULAR; INJECTION               |           | 20           |             | 03/13/86         | 600  | 0.25% - 5.0%   |
| INTRAVENOUS; SOLUTION, INJECTION       |           | 1            |             |                  |      |                |
| IV(INFUSION); INJECTION                |           | 5            |             | 11/19/80         | 510  | 0.5%           |
| NASAL; SOLUTION                        |           | 3            |             | 02/21/78         | 510  | 0.05% - 0.5%   |
| NASAL; SPRAY, METERED                  |           | 2            |             | 03/07/94         | 510  |                |
| NERVE BLOCK; INJECTION                 |           | 2            |             | 11/15/79         | 600  | 0.25% - 0.5%   |
| OPHTHALMIC; OINTMENT                   |           | 5            |             | 12/01/89         | LINK | 0.5%           |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION |           | 1            |             |                  |      |                |
| OPHTHALMIC; SOLUTION                   |           | 4            |             |                  |      |                |
| OTIC; SOLUTION                         |           | 1            |             | 08/31/81         | 600  | 0.2% - 0.5%    |
| SUBCUTANEOUS; INJECTION                |           | 1            |             |                  |      |                |
| TOPICAL; SOLUTION                      |           | 1            |             |                  |      |                |
| CHLOROBUTANOL HEMIHYDRATE              | 006001645 |              |             |                  |      |                |
| INTRAMUSCULAR; INJECTION               |           | 1            |             |                  |      |                |
| CHLOROBUTANOL, ANHYDROUS               | 001320667 |              |             |                  |      |                |
| OPHTHALMIC; SOLUTION                   |           | 1            |             |                  |      |                |
| CHLOROCRESOL                           | 000059507 |              |             |                  |      |                |
| TOPICAL; CREAM, AUGMENTED              |           | 1            |             |                  |      |                |
| TOPICAL; EMULSION, CREAM               |           | 21           |             | 08/03/94         | 600  | 0.075% - 0.75% |
| CHLOROXYLENOL                          | 000088040 |              |             |                  |      |                |
| TOPICAL; EMULSION, CREAM               |           | 1            |             |                  |      |                |
| CHOLESTEROL                            | 000057885 |              |             |                  |      |                |
| INTRAVENOUS; SUSPENSION, INJECTION     |           | 1            |             |                  |      |                |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION |           | 1            |             |                  |      |                |
| TOPICAL; EMULSION, CREAM               |           | 1            |             |                  |      |                |
| TOPICAL; LOTION                        |           | 1            |             |                  |      |                |
| TOPICAL; OINTMENT                      |           | 3            |             | 05/18/65         | 600  | 0.9% - 5.0%    |
| VAGINAL; EMULSION, CREAM               |           | 3            |             | 06/09/86         | 600  | 0.3% - 0.5%    |
| CHOLETH                                |           |              |             |                  |      |                |
| VAGINAL; EMULSION, CREAM               |           | 2            |             | 07/23/82         | 600  | 0.4%           |
| CINNAMALDEHYDE                         | 000104552 |              |             |                  |      |                |
| ORAL; SUSPENSION                       |           | 1            |             |                  |      |                |
| ORAL; TABLET                           |           | 1            |             |                  |      |                |
| CINNAMON                               |           |              |             |                  |      |                |
| ORAL; SOLUTION, ELIXIR                 |           | 1            |             |                  |      |                |
| CINNAMON OIL                           | 008007805 |              |             |                  |      |                |
| ORAL; PASTILLE                         |           | 1            |             |                  |      |                |
| ORAL; SOLUTION, ELIXIR                 |           | 9            |             | 12/16/83         | 600  | 0.011%         |
| ORAL; SUSPENSION                       |           | 1            |             |                  |      |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| CITRIC ACID                                    | 000077929 |              |             |                  |     |                 |
| CAUDAL BLOCK; INJECTION                        |           | 1            |             |                  |     |                 |
| EPIDURAL; INJECTION                            |           | 5            |             |                  |     |                 |
| IM - IV - SC; INJECTION                        |           | 10           |             | 02/26/93         | 600 | 0.02%           |
| IM - IV; INJECTION                             |           | 21           |             | 08/23/95         | 600 | 0.063% - 1.26%  |
| IM - IV; SOLUTION, INJECTION                   |           | 1            |             | 08/31/90         | 600 | 0.01% - 0.8%    |
| IM - SC; INJECTION                             |           | 1            |             |                  |     |                 |
| INHALATION; SOLUTION                           |           | 4            |             |                  |     |                 |
| INTRA-ARTERIAL; SOLUTION, INJECTION            |           | 1            |             | 02/19/92         | UNK | 0.44042% - 1.0% |
| INTRA-ARTICULAR; INJECTION                     |           | 8            |             |                  |     |                 |
| INTRABURSAL; INJECTION                         |           | 4            |             | 04/09/86         | 600 | 0.205%          |
| INTRACARDIAC; INJECTION                        |           | 1            |             | 02/13/74         | 600 | 1.0%            |
| INTRALESIONAL; INJECTION                       |           | 2            |             |                  |     |                 |
| INTRAMUSCULAR; INJECTION                       |           | 17           |             | 02/11/84         | 600 |                 |
| INTRAPLEURAL; INJECTION                        |           | 1            |             | 04/03/87         | 600 | 0.02% - 2.0%    |
| INTRASYNOVIAL; INJECTION                       |           | 2            |             |                  |     |                 |
| INTRATHECAL; INJECTION                         |           | 1            |             | 02/17/84         | 600 | 1.0%            |
| INTRAVASCULAR; SOLUTION, INJECTION             |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                         |           | 28           |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 3            |             | 12/15/95         | 600 | 0.0175% - 0.86% |
| INTRAVENOUS; SOLUTION, INJECTION               |           | 1            |             | 07/12/88         | 600 |                 |
| IONTOPHORESIS; SOLUTION                        |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                        |           | 32           |             |                  |     |                 |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 2            |             | 08/30/95         | 600 | 0.0229% - 1.0%  |
| NASAL; SOLUTION                                |           | 1            |             | 08/31/95         | 600 |                 |
| NASAL; SPRAY, METERED                          |           | 3            |             |                  |     |                 |
| NERVE BLOCK; INJECTION                         |           | 15           |             | 03/08/95         | UNK | 0.1%            |
| OPHTHALMIC; SOLUTION                           |           | 5            |             | 02/26/93         | 600 | 0.02%           |
| OPHTHALMIC; SUSPENSION                         |           | 4            |             | 01/04/95         | 600 | 0.035% - 0.05%  |
| ORAL; CAPSULE                                  |           | 6            |             | 05/09/89         | 600 |                 |
| ORAL; CAPSULE, HARD GELATIN                    |           | 1            |             | 08/18/95         | 600 | 5.0MG - 12.8MG  |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 2            |             |                  |     |                 |
| ORAL; CONCENTRATE                              |           | 10           |             | 12/30/86         | 150 | 0.015MG - 1.0MG |
| ORAL; DROPS                                    |           | 3            |             | 01/30/92         | 600 | 0.05% - 0.24%   |
| ORAL; GRANULE                                  |           | 4            |             | 05/25/95         | UNK | 0.18%           |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             | 04/15/88         | 600 |                 |
| ORAL; POWDER                                   |           | 2            |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 28           |             | 12/05/88         | 510 | 0.0005%         |
| ORAL; SOLUTION                                 |           | 32           |             | 12/23/93         | 530 |                 |
| ORAL; SOLUTION, ELIXIR                         |           | 15           |             | 11/17/95         | 530 | 0.0121% - 0.65% |
| ORAL; SUSPENSION                               |           | 30           |             | 10/27/92         | 600 | 0.0299% - 0.15% |
| ORAL; SYRUP                                    |           | 79           |             | 06/16/95         | UNK | 0.1% - 0.2%     |
| ORAL; TABLET                                   |           | 33           |             | 09/25/95         | 600 | 0.1% - 7.3519%  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 5            |             | 03/20/92         | 600 | 0.06MG - 20.0MG |
| ORAL; TABLET, COATED                           |           | 2            |             | 11/16/94         | UNK | 0.2MG - 2.13MG  |
| ORAL; TABLET, FILM COATED                      |           | 9            |             | 04/08/81         | 600 |                 |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             | 12/23/91         | 510 | 1.25MG - 20.0MG |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM     | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|-------------------------------------|-----------|--------------|-------------|------------------|-----|----------------|
| CITRIC ACID                         | 000077929 |              |             |                  |     |                |
| ORAL-28; TABLET                     |           | 1            |             |                  |     |                |
| OTIC; SOLUTION                      |           | 4            |             | 10/31/94         | 600 | 0.05% - 0.2%   |
| OTIC; SOLUTION, DROPS               |           | 1            |             |                  |     |                |
| SOFT TISSUE; INJECTION              |           | 2            |             | 02/21/99         | 600 | 0.205%         |
| SUBLINGUAL; TABLET                  |           | 2            |             | 08/11/81         | 600 |                |
| TOPICAL; EMULSION, AEROSOL FOAM     |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM            |           | 32           |             | 04/13/95         | 600 | 0.001% - 0.85% |
| TOPICAL; GEL                        |           | 1            |             |                  |     |                |
| TOPICAL; LOTION                     |           | 9            |             | 01/24/92         | 600 | 0.21% - 0.85%  |
| TOPICAL; OINTMENT                   |           | 3            |             | 09/30/83         | UNK | 0.001%         |
| TOPICAL; POWDER, FOR RECONSTITUTION |           | 1            |             |                  |     |                |
| TOPICAL; SHAMPOO                    |           | 2            |             | 08/21/90         | UNK | 0.075%         |
| TOPICAL; SOLUTION                   |           | 24           |             | 02/27/95         | 600 | 0.005% - 0.4%  |
| TOPICAL; SUSPENSION, SHAMPOO        |           | 3            |             | 01/10/91         | 600 | 0.77758%       |
| TOPICAL; SWAB                       |           | 2            |             | 07/23/87         | 600 | 0.04%          |
| VAGINAL; EMULSION, CREAM            |           | 1            |             |                  |     |                |
| CITRIC ACID MONOHYDRATE             | 005949291 |              |             |                  |     |                |
| IM - IV - SC; INJECTION             |           | 1            |             |                  |     |                |
| INTRACARDIAC; INJECTION             |           | 1            |             |                  |     |                |
| INTRAVENOUS; INJECTION              |           | 3            |             | 08/18/95         | 110 | 0.075%         |
| IV(INFUSION); INJECTION             |           | 6            |             | 08/18/95         | 110 | 0.05% - 0.075% |
| NASAL; SOLUTION                     |           | 1            |             |                  |     |                |
| NERVE BLOCK; INJECTION              |           | 1            |             |                  |     |                |
| ORAL; SUSPENSION                    |           | 1            |             |                  |     |                |
| ORAL; SYRUP                         |           | 2            |             | 06/10/87         | UNK |                |
| TOPICAL; EMULSION, CREAM            |           | 2            |             | 02/16/94         | 600 | 0.05%          |
| TOPICAL; GEL                        |           | 1            |             |                  |     |                |
| TOPICAL; SUSPENSION, SHAMPOO        |           | 1            |             |                  |     |                |
| VAGINAL; EMULSION, CREAM            |           | 1            |             |                  |     |                |
| CITRIC ACID, ANHYDROUS              |           |              |             |                  |     |                |
| IM - IV; INJECTION                  |           | 1            |             |                  |     |                |
| ORAL; SOLUTION                      |           | 1            |             |                  |     |                |
| ORAL; SYRUP                         |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM            |           | 1            |             |                  |     |                |
| CITRIC ACID, HYDROUS                | 015686654 |              |             |                  |     |                |
| INTRAVENOUS; INJECTION              |           | 1            |             |                  |     |                |
| ORAL; GRANULE, FOR RECONSTITUTION   |           | 1            |             |                  |     |                |
| ORAL; SOLUTION                      |           | 1            |             |                  |     |                |
| ORAL; SYRUP                         |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM            |           | 4            |             | 06/17/94         | UNK | 0.02% - 0.05%  |
| CLOVE OIL                           | 008000348 |              |             |                  |     |                |
| ORAL; SOLUTION                      |           | 1            |             |                  |     |                |
| ORAL; SOLUTION, ELIXIR              |           | 8            |             | 12/16/83         | 600 | 0.008%         |
| ORAL; SUSPENSION                    |           | 2            |             | 12/27/91         | 600 | 0.001%         |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV      | POTENCY RANGE      |                   |
|--|-----------|--------------|-------------|------------------|----------|--------------------|-------------------|
| COCAMIDE DIETHANOLAMINE                        | 061791319 |              |             |                  |          |                    |                   |
| TOPICAL; EMULSION, AEROSOL FOAM                |           | 1            |             |                  |          |                    |                   |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |          |                    |                   |
| TOPICAL; LOTION                                |           | 1            |             |                  |          |                    |                   |
| TOPICAL; SHAMPOO                               |           | 1            |             |                  |          |                    |                   |
| TOPICAL; SOLUTION                              |           | 4            |             |                  | 04/15/91 | 600                | 2.0% - 4.0%       |
| TOPICAL; SPONGE                                |           | 2            |             | 02/28/91         | 600      | 2.0MG              |                   |
| COCAMIDE ETHER SULFATE                         | 061788907 |              |             |                  |          |                    |                   |
| TOPICAL; SHAMPOO                               |           | 1            |             |                  |          |                    |                   |
| COCAMINE OXIDE                                 |           |              |             |                  |          |                    |                   |
| TOPICAL; SHAMPOO                               |           | 1            |             |                  |          |                    |                   |
| COCOA BUTTER                                   |           |              |             |                  |          |                    |                   |
| RECTAL; SUPPOSITORY                            |           | 4            |             | 10/04/83         | 600      | 1.868GM - 2.0265GM |                   |
| COCOA BUTTER (POND'S TYPE 520A)                |           |              |             |                  |          |                    |                   |
| RECTAL; SUPPOSITORY                            |           | 1            |             |                  |          |                    |                   |
| TOPICAL; LOTION                                |           | 1            |             |                  |          |                    |                   |
| COCOAMPHOCARBOXYGLYCINATE                      |           |              |             |                  |          |                    |                   |
| TOPICAL; SUSPENSION, SHAMPOO                   |           | 1            |             |                  |          |                    |                   |
| COCOLYCIDES                                    |           |              |             |                  |          |                    |                   |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |          |                    |                   |
| COCONUT OIL                                    | 008001318 |              |             |                  |          |                    |                   |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |          |                    |                   |
| TOPICAL; OINTMENT                              |           | 2            |             | 09/30/94         | 600      |                    |                   |
| COCONUT OIL, HYDROGENATED                      |           |              |             |                  |          |                    |                   |
| RECTAL; SUPPOSITORY                            |           | 3            |             | 11/24/93         | 600      |                    |                   |
| COLORING SUSPENSION                            |           |              |             |                  |          |                    |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |          |                    |                   |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |          |                    |                   |
| CONFECTIONERS GLAZE                            |           |              |             |                  |          |                    |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |          |                    |                   |
| CORIANDE OIL                                   | 008008524 |              |             |                  |          |                    |                   |
| ORAL; SOLUTION                                 |           | 1            |             |                  |          |                    |                   |
| ORAL; SOLUTION, ELIXIR                         |           | 8            |             | 12/16/83         | 600      | 0.003%             |                   |
| CORN GLYCERIDES                                |           |              |             |                  |          |                    |                   |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |          |                    |                   |
| ORAL; SOLUTION                                 |           | 1            |             |                  |          |                    |                   |
| CORN OIL                                       | 008001307 |              |             |                  |          |                    |                   |
| ORAL; CAPSULE                                  |           | 6            |             |                  | 06/29/93 | 600                | 205.0MG - 918.0MG |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |          |                    |                   |
| ORAL; TABLET                                   |           | 15           |             |                  | 03/21/77 | 600                | 0.02GM            |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |          |                    |                   |
| CORN OIL PEG-6 ESTERS                          |           |              |             |                  |          |                    |                   |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |          |                    |                   |
| CORN SYRUP                                     |           |              |             |                  |          |                    |                   |
| ORAL; SYRUP                                    |           | 7            |             | 10/28/94         | 600      |                    |                   |
| ORAL; TABLET                                   |           | 3            |             | 12/03/73         | 600      | 8.0MG - 14.065MG   |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |          |                    |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| CORN SYRUP  |           |              |             |                  |     |                  |
| ORAL; TABLET, UNCOATED, TROCHE                          |           | 1            |             |                  |     |                  |
| COTTONSEED OIL  | 008001294 |              |             |                  |     |                  |
| INTRAMUSCULAR; INJECTION                                |           | 7            |             | 03/13/86         | 600 | 56.0% - 91.66%   |
| COTTONSEED OIL, HYDROGENATED                            |           |              |             |                  |     |                  |
| ORAL; CAPSULE   |           | 3            |             | 08/04/86         | 600 | 2.5MG - 4.25MG   |
| ORAL; TABLET  |           | 46           |             | 08/30/91         | 600 | 0.002MG - 26.0MG |
| ORAL; TABLET, COATED                                    |           | 1            |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 5            |             | 08/14/87         | 600 | 32.4MG - 402.0MG |
| CREAM BASE  |           |              |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM                                |           | 2            |             | 05/15/85         | 600 |                  |
| CREATINE  | 000057001 |              |             |                  |     |                  |
| INTRA-ARTICULAR; INJECTION                              |           | 1            |             |                  |     |                  |
| INTRALESIONAL; INJECTION                                |           | 1            |             |                  |     |                  |
| INTRAMUSCULAR; INJECTION                                |           | 1            |             |                  |     |                  |
| CREATININE  | 000060275 |              |             |                  |     |                  |
| IM - IV - SC; INJECTION                                 |           | 1            |             |                  |     |                  |
| IM - IV; INJECTION                                      |           | 4            |             | 07/01/82         | 600 | 0.8%             |
| INTRA-ARTICULAR; INJECTION                              |           | 4            |             | 05/24/82         | 600 | 0.5% - 0.8%      |
| INTRABURSAL; INJECTION                                  |           | 1            |             |                  |     |                  |
| INTRADERMAL; INJECTION, SUSTAINED ACTION                |           | 1            |             |                  |     |                  |
| INTRALESIONAL; INJECTION                                |           | 3            |             | 06/19/80         | 600 | 0.8%             |
| INTRAMUSCULAR; INJECTION                                |           | 1            |             |                  |     |                  |
| INTRASYNOVIAL; INJECTION                                |           | 2            |             | 03/01/77         | UNK | 0.8%             |
| OPHTHALMIC; SOLUTION                                    |           | 1            |             |                  |     |                  |
| OTIC; SOLUTION  |           | 1            |             |                  |     |                  |
| SOFT TISSUE; INJECTION                                  |           | 3            |             | 05/24/82         | 600 | 0.5% - 0.8%      |
| TOPICAL; EMULSION, CREAM                                |           | 1            |             |                  |     |                  |
| CRESOL, M-  | 000108394 |              |             |                  |     |                  |
| IM - SC; INJECTION                                      |           | 2            |             | 01/23/85         | 510 | 0.158% - 0.25%   |
| INTRADERMAL; INJECTION                                  |           | 1            |             |                  |     |                  |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION, LYOPHILI |           | 1            |             |                  |     |                  |
| SUBCUTANEOUS; INJECTION                                 |           | 10           |             | 03/31/94         | 510 | 0.15% - 0.31%    |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION, LYOPHILI  |           | 1            |             |                  |     |                  |
| SUBCUTANEOUS; SUSPENSION, INJECTION                     |           | 1            |             |                  |     |                  |
| CROSCARMELOSE SODIUM                                    |           |              |             |                  |     |                  |
| ORAL; CAPSULE   |           | 59           |             | 07/03/95         | 600 | 0.4MG - 21.0MG   |
| ORAL; CAPSULE, HARD GELATIN                             |           | 1            |             |                  |     |                  |
| ORAL; GRANULE, FOR RECONSTITUTION                       |           | 1            |             |                  |     |                  |
| ORAL; TABLET  |           | 450          |             | 11/09/95         | 600 | 0.013GM          |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,          |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                                    |           | 3            |             | 12/30/92         | 110 | 4.75MG - 33.0MG  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED            |           | 8            |             | 11/30/95         | 600 | 2.0MG - 32.44MG  |
| ORAL; TABLET, FILM COATED                               |           | 22           |             | 12/12/95         | 120 | 1.5MG - 40.0MG   |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 1            |             |                  |     |                  |
| ORAL-21; TABLET   |           | 1            |             |                  |     |                  |
| ORAL-28; TABLET   |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| CROSCARMELLOSE SODIUM<br>SUBLINGUAL; TABLET                                  |           | 5            |             | 09/18/86         | 600 | 1.8MG - 6.5MG   |
| CROSPROVIDONE<br>IMPLANTATION; PELLET  | 009003398 | 1            |             |                  |     |                 |
| ORAL; CAPSULE  |           | 6            |             | 03/03/95         | 110 | 1.5MG - 20.0MG  |
| ORAL; CAPSULE, SUSTAINED ACTION  |           | 12           |             | 04/25/85         | UNK | 0.5MG - 10.71MG |
| ORAL; GRANULE, EFFERVESCENT  |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |                 |
| ORAL; TABLET   |           | 131          |             | 12/27/95         | 600 | 1.3MG - 180.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                               |           | 1            |             |                  |     |                 |
| ORAL; TABLET, COATED   |           | 14           |             | 02/28/95         | 600 | 1.64MG - 28.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                                 |           | 1            |             |                  |     |                 |
| ORAL; TABLET, ENTERIC COATED PARTICLES                                       |           | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED  |           | 14           |             | 09/29/95         | 600 | 2.0MG - 55.3MG  |
| ORAL; TABLET, SUSTAINED ACTION   |           | 7            |             | 12/15/89         | 110 | 3.0MG - 144.0MG |
| ORAL-21; TABLET  |           | 1            |             |                  |     |                 |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                 |
| VAGINAL; SUPPOSITORY   |           | 1            |             |                  |     |                 |
| VAGINAL; TABLET  |           | 1            |             |                  |     |                 |
| CUPRIC SULFATE<br>OTIC; SOLUTION   | 007758998 | 1            |             |                  |     |                 |
| OTIC; SUSPENSION   |           | 1            |             |                  |     |                 |
| CUPRIC SULFATE, ANHYDROUS<br>OTIC; SOLUTION                                  | 007758987 | 1            |             |                  |     |                 |
| CYCLOMETHICONE<br>ORAL; POWDER, FOR RECONSTITUTION                           |           | 1            |             |                  |     |                 |
| TOPICAL; CREAM, AUGMENTED  |           | 1            |             |                  |     |                 |
| CYSTEINE<br>IM - SC; INJECTION, SUSTAINED ACTION                             |           | 1            |             |                  |     |                 |
| CYSTEINE HYDROCHLORIDE<br>INTRAVENOUS; INJECTION                             | 007048046 | 1            |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                                  |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE  |           | 1            |             |                  |     |                 |
| DC ANTIFOAM AF TRITURATION 1% ON SUCROSE<br>ORAL; POWDER, FOR RECONSTITUTION |           | 1            |             |                  |     |                 |
| DEHYDROACETIC ACID<br>TOPICAL; LOTION  | 000520456 | 2            |             | 11/26/85         | 600 | 0.1%            |
| DEHYMULS E<br>TOPICAL; OINTMENT  |           | 2            |             | 12/17/90         | UNK | 5.0% - 7.5%     |
| DENATONIUM BENZOATE<br>TOPICAL; GEL  | 003734336 | 1            |             |                  |     |                 |
| DEOXYCHOLIC ACID<br>IV(INFUSION); POWDER, FOR INJECTION SOLUTION             | 000083443 | 1            |             |                  |     |                 |
| DEXTRATES<br>ORAL; TABLET  |           | 2            |             | 11/30/95         | 600 | 54.0MG - 86.5MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                               |           | 1            |             |                  |     |                 |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE        |
|--|-----------|--------------|-------------|------------------|-----|----------------------|
| DEXTRIN  | 009004539 |              |             |                  |     |                      |
| ORAL; TABLET                                   |           | 3            |             | 11/13/84         | 600 | 1.56MG - 1.8MG       |
| TOPICAL; EMULSION, CREAM                       |           | 3            |             | 09/28/92         | 600 |                      |
| TOPICAL; SHAMPOO                               |           | 1            |             |                  |     |                      |
| DEXTRINS MODIFIED                              |           |              |             |                  |     |                      |
| ORAL-28; TABLET                                |           | 2            |             | 04/30/73         | 510 |                      |
| DEXTROSE                                       | 005996101 |              |             |                  |     |                      |
| IM - IV - SC; INJECTION                        |           | 1            |             |                  |     |                      |
| IM - IV; INJECTION                             |           | 3            |             | 07/23/86         | 520 | 3.6% - 5.0%          |
| IM - IV; POWDER, FOR INJECTION SOLUTION        |           | 5            |             | 12/27/91         | 600 |                      |
| IM - SC; INJECTION                             |           | 2            |             | 07/25/83         | 600 | 3.75%                |
| INTERSTITIAL; INJECTION                        |           | 1            |             |                  |     |                      |
| INTRACAVITARY; INJECTION                       |           | 1            |             |                  |     |                      |
| INTRAMUSCULAR; INJECTION                       |           | 3            |             |                  |     |                      |
| INTRAPERITONEAL; INJECTION                     |           | 1            |             | 05/24/79         | 600 | 4.4% - 5.0%          |
| INTRAPLEURAL; INJECTION                        |           | 1            |             |                  |     |                      |
| INTRAVENOUS; INJECTION                         |           | 13           |             | 07/30/93         | 520 | 2.0% - 5.0%          |
| INTRAVENOUS; SOLUTION, INJECTION               |           | 2            |             | 01/22/92         | UNK | 5.0%                 |
| IV(INFUSION); INJECTION                        |           | 39           |             | 01/31/95         | 180 | 1.4% - 5.0%          |
| IV(INFUSION); SOLUTION, INJECTION              |           | 3            |             | 12/29/92         | 520 | 2.2% - 3.8%          |
| NASAL; SPRAY, METERED                          |           | 3            |             | 10/19/94         | UNK | 5.0%                 |
| ORAL; CONCENTRATE                              |           | 2            |             | 10/16/87         | 600 | 5.0% - 14.32708%     |
| ORAL; PASTILLE                                 |           | 1            |             |                  |     |                      |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                      |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                      |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                      |
| ORAL; TABLET                                   |           | 6            |             | 09/27/93         | 600 | 72.459MG - 150.0MG   |
| ORAL; TABLET, UNCOATED, TROCHE                 |           | 1            |             |                  |     |                      |
| SPINAL; INJECTION                              |           | 6            |             | 12/11/87         | 600 | 7.5% - 8.25%         |
| SUBLINGUAL; TABLET                             |           | 1            |             |                  |     |                      |
| DEXTROSE SOLUTION                              | 008012246 |              |             |                  |     |                      |
| INTRAVENOUS; INJECTION                         |           | 1            |             |                  |     |                      |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                      |
| IV(INFUSION); SOLUTION, INJECTION              |           | 1            |             |                  |     |                      |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                      |
| DEXTROSE, ANHYDROUS                            | 000050997 |              |             |                  |     |                      |
| INTRAVENOUS; INJECTION                         |           | 1            |             |                  |     |                      |
| INTRAVENOUS; SOLUTION, INJECTION               |           | 1            |             |                  |     |                      |
| IV(INFUSION); INJECTION                        |           | 5            |             | 08/09/94         | 110 | 4.5% - 4.94%         |
| IV(INFUSION); SOLUTION, INJECTION              |           | 1            |             |                  |     |                      |
| DI-PAC (97% SUCROSE-3% MODIFIED DEXTRINS)      |           |              |             |                  |     |                      |
| ORAL; TABLET                                   |           | 5            |             | 03/18/80         | 600 | 51.0MG - 322.35MG    |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 10/04/76         | 600 | 162.674MG - 260.12MG |
| ORAL; TABLET, COATED                           |           | 3            |             | 03/07/77         | 600 | 24.8MG - 105.4MG     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE         |
|--|-----------|--------------|-------------|------------------|-----|-----------------------|
| DIACETYLATED MONOGLYCERIDES                  | 008029923 | 48           |             | 11/05/92         | 600 | 0.00003ML - 0.00006ML |
| ORAL; TABLET                                 |           | 2            |             | 04/08/81         | 600 |                       |
| ORAL; TABLET, COATED                         |           | 1            |             |                  |     |                       |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 6            |             | 05/31/91         | 600 | 0.04MG - 1.1MG        |
| ORAL; TABLET, FILM COATED                    |           | 1            |             |                  |     |                       |
| DIATOMACEOUS EARTH                           |           |              |             |                  |     |                       |
| ORAL; TABLET, SUSTAINED ACTION               |           | 1            |             |                  |     |                       |
| DIATRIZOIC ACID                              | 000117964 | 2            |             | 08/29/74         | 160 |                       |
| INTRA-ARTERIAL; INJECTION                    |           | 1            |             |                  |     |                       |
| INTRA-ARTICULAR; INJECTION                   |           | 1            |             |                  |     |                       |
| INTRACARDIAC; INJECTION                      |           | 1            |             |                  |     |                       |
| INTRADISCAL; INJECTION                       |           | 1            |             |                  |     |                       |
| INTRAUTERINE; SOLUTION                       |           | 2            |             | 08/29/74         | 160 |                       |
| INTRAVENOUS; INJECTION                       |           | 1            |             |                  |     |                       |
| IV(INFUSION); INJECTION                      |           | 1            |             |                  |     |                       |
| PERIARTICULAR; INJECTION                     |           | 1            |             |                  |     |                       |
| URETERAL; SOLUTION                           |           | 1            |             |                  |     |                       |
| DIAZOLYDINYLUREA                             |           | 2            |             | 12/27/90         | UNK | 0.2%                  |
| TOPICAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                       |
| TOPICAL; LOTION                              |           |              |             |                  |     |                       |
| DIBUTYL PHTHALATE                            | 000084742 | 1            |             |                  |     |                       |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           |              |             |                  |     |                       |
| DIBUTYL SEBACATE                             | 000109433 | 2            |             | 08/19/88         | 600 |                       |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 1            |             |                  |     |                       |
| ORAL; GRANULE, ENTERIC COATED                |           | 2            |             | 10/05/90         | 600 |                       |
| ORAL; TABLET, FILM COATED                    |           | 1            |             |                  |     |                       |
| ORAL; TABLET, SUSTAINED ACTION               |           |              |             |                  |     |                       |
| DICHLORODIFLUOROMETHANE                      | 000075718 | 24           |             | 12/28/95         | 600 | 11.25% - 68.5611%     |
| INHALATION; AEROSOL, METERED                 |           | 1            |             |                  |     |                       |
| NASAL; AEROSOL SPRAY                         |           | 4            |             | 02/14/94         | UNK | 99.789%               |
| NASAL; AEROSOL, METERED                      |           | 1            |             |                  |     |                       |
| ORAL; AEROSOL                                |           | 1            |             |                  |     |                       |
| RECTAL; EMULSION, AEROSOL FOAM               |           | 1            |             |                  |     |                       |
| TOPICAL; AEROSOL                             |           | 1            |             |                  |     |                       |
| TOPICAL; EMULSION, AEROSOL FOAM              |           |              |             |                  |     |                       |
| DICHLOROFLUOROMETHANE                        | 000075434 | 1            |             |                  |     |                       |
| ORAL; AEROSOL SPRAY                          |           |              |             |                  |     |                       |
| DICHLOROTETRAFLUOROETHANE                    | 000076142 | 15           |             | 12/30/92         | UNK | 21.857% - 51.12%      |
| INHALATION; AEROSOL, METERED                 |           | 1            |             |                  |     |                       |
| NASAL; AEROSOL SPRAY                         |           | 1            |             |                  |     |                       |
| NASAL; AEROSOL, METERED                      |           | 1            |             |                  |     |                       |
| ORAL; AEROSOL                                |           | 1            |             |                  |     |                       |
| RECTAL; EMULSION, AEROSOL FOAM               |           | 2            |             | 05/17/88         | 600 | 50.0%                 |
| TOPICAL; AEROSOL                             |           | 1            |             |                  |     |                       |
| TOPICAL; EMULSION, AEROSOL FOAM              |           |              |             |                  |     |                       |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|--|-----------|--------------|-------------|------------------|-----|----------------|
| DICYCLOHEXYL-CARBODIIMIDE                      |           |              |             |                  |     |                |
| IM - IV; POWDER, FOR INJECTION SOLUTION        |           | 1            |             |                  |     |                |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                |
| DIETHANOLAMINE                                 | 000111422 |              |             |                  |     |                |
| IV(INFUSION); INJECTION                        |           | 8            |             | 09/11/92         | 600 | 0.3% - 0.35%   |
| DIETHYL PHTHALATE                              | 000084662 |              |             |                  |     |                |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 7            |             | 01/04/95         | 600 | 8.0MG - 12.0MG |
| DIETHYL SEBACATE                               | 000110407 |              |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                |
| DIETHYLAMINE                                   |           |              |             |                  |     |                |
| IM - IV; POWDER, FOR INJECTION SOLUTION        |           | 1            |             |                  |     |                |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                |
| DIGLYCERIDES                                   |           |              |             |                  |     |                |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                |
| DIGLYCOL STEARATE                              | 000106116 |              |             |                  |     |                |
| VAGINAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                |
| DIHYDROXYALUMINUM SODIUM CARBONATE             | 000539684 |              |             |                  |     |                |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                |
| DIISOPROPANOLAMINE                             | 000110974 |              |             |                  |     |                |
| TOPICAL; GEL                                   |           | 1            |             |                  |     |                |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                |
| DIISOPROPYL ADIPATE                            | 006938949 |              |             |                  |     |                |
| TOPICAL; LOTION                                |           | 2            |             | 06/05/78         | 600 |                |
| TOPICAL; SOLUTION                              |           | 4            |             | 02/27/95         | 600 | 10.0%          |
| DIISOPROPYLBENZOTHAZYL-2-SULFENAMIDE           |           |              |             |                  |     |                |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                |
| DIMETHICONE                                    | 009006659 |              |             |                  |     |                |
| ORAL; CAPSULE                                  |           | 4            |             | 08/29/95         | 600 | 2.5MG - 8.2MG  |
| ORAL; TABLET                                   |           | 3            |             | 08/17/88         | 600 | 0.2MG          |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                       |           | 2            |             | 08/26/59         | UNK |                |
| TOPICAL; LOTION                                |           | 2            |             | 12/07/92         | UNK | 0.4%           |
| DIMETHICONE 350                                | 009006659 |              |             |                  |     |                |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                       |           | 3            |             | 01/24/80         | UNK | 1.0%           |
| DIMETHICONE 360                                |           |              |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                |
| DIMETHYLDIOCTADECYLAMMONIUM BENTONITE          |           |              |             |                  |     |                |
| RECTAL; SUSPENSION                             |           | 1            |             |                  |     |                |
| DIMYRISTOYL LECITHIN                           | 018194246 |              |             |                  |     |                |
| IV(INFUSION); SUSPENSION, INJECTION            |           | 1            |             |                  |     |                |
| DIMYRISTOYL PHOSPHATIDYLGLYCEROL, L-           | 057618287 |              |             |                  |     |                |
| IV(INFUSION); SUSPENSION, INJECTION            |           | 1            |             |                  |     |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                             | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| DIOCTYLPHTHALATE<br>OPHTHALMIC; DRUG DELIVERY SYSTEM        |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SUPPOSITORY, INSERT, CONTROLLED RELEASE         |           | 1            |             |                  |     |                  |
| DIPROPYLENE GLYCOL<br>TRANSDERMAL; FILM, CONTROLLED RELEASE | 000110985 | 1            |             |                  |     |                  |
| DISODIUM EDISYLATE<br>ORAL; SOLUTION                        |           | 1            |             |                  |     |                  |
| ORAL; SYRUP   |           | 1            |             |                  |     |                  |
| ORAL; TABLET  |           | 1            |             |                  |     |                  |
| DISODIUM MONOOLEAMIDE SULFASUCCINATE<br>TOPICAL; SHAMPOO    |           | 1            |             |                  |     |                  |
| DISOFENIN<br>IV(INFUSION); INJECTION                        | 065717977 | 1            |             |                  |     |                  |
| DOCUSATE<br>ORAL; TABLET                                    | 010041197 | 1            |             |                  |     |                  |
| DOCUSATE SODIUM<br>INTRAMUSCULAR; INJECTION                 | 000577117 | 1            |             |                  |     |                  |
| ORAL; CAPSULE   |           | 11           |             | 08/19/91         | 600 | 0.4MG - 2.0MG    |
| ORAL; CAPSULE, SUSTAINED ACTION                             |           | 1            |             |                  |     |                  |
| ORAL; GRANULE FOR RECONSTITUTION, CR                        |           | 1            |             |                  |     |                  |
| ORAL; SUSPENSION  |           | 2            |             | 01/26/84         | 600 | 0.04%            |
| ORAL; TABLET  |           | 47           |             | 12/29/95         | 600 | 0.002MG - 11.0MG |
| TOPICAL; GEL  |           | 2            |             | 10/26/84         | UNK |                  |
| TOPICAL; SHAMPOO  |           | 1            |             |                  |     |                  |
| DOCUSATE SODIUM/SODIUM BENZOATE<br>ORAL; CAPSULE            |           | 4            |             | 06/03/87         | 600 | 0.425MG - 4.0MG  |
| ORAL; TABLET  |           | 16           |             | 10/20/95         | 600 | 0.2MG - 6.0MG    |
| DRI KLEAR 042<br>ORAL; TABLET                               |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED  |           | 1            |             |                  |     |                  |
| DRY FLO<br>ORAL; TABLET                                     |           | 1            |             |                  |     |                  |
| DURO-TAK 280-2516<br>TRANSDERMAL; FILM, CONTROLLED RELEASE  |           | 1            |             |                  |     |                  |
| DURO-TAK 80-1196<br>TRANSDERMAL; FILM, CONTROLLED RELEASE   |           | 1            |             |                  |     |                  |
| DUSTING POWDER<br>ORAL; TABLET                              |           | 3            |             | 04/14/83         | 600 |                  |
| ORAL; TABLET, COATED  |           | 1            |             |                  |     |                  |
| DYE BEIGE P-1437<br>ORAL; TABLET                            |           | 1            |             |                  |     |                  |
| DYE BLACK<br>ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| ORAL; TABLET  |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                    | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|--|-----------|--------------|-------------|------------------|-----|----------------|
| DYE BLACK LB-442<br>ORAL; TABLET                   |           | 1            |             |                  |     |                |
| DYE BLUE<br>ORAL; CAPSULE                          |           | 2            |             | 09/10/80         | 600 | 0.014MG        |
| ORAL; TABLET                                       |           | 1            |             |                  |     |                |
| RECTAL; SUPPOSITORY                                |           | 1            |             |                  |     |                |
| DYE BLUE #1<br>ORAL; CAPSULE                       |           | 3            |             | 05/31/90         | 520 |                |
| ORAL; TABLET                                       |           | 1            |             |                  |     |                |
| ORAL; TABLET, SUSTAINED ACTION                     |           | 1            |             |                  |     |                |
| DYE BLUE #2<br>ORAL; TABLET, SUSTAINED ACTION      |           | 1            |             |                  |     |                |
| DYE BROWN LAKE<br>ORAL; TABLET                     |           | 1            |             |                  |     |                |
| DYE BROWN LB-292<br>ORAL; TABLET                   |           | 1            |             |                  |     |                |
| DYE BROWN LB-464<br>ORAL; TABLET                   |           | 1            |             |                  |     |                |
| DYE CARAMEL<br>ORAL; SYRUP                         |           | 4            |             | 07/26/88         | UNK | 0.025% - 0.05% |
| DYE CARAMEL ACID PROOF 100<br>ORAL; SYRUP          |           | 1            |             |                  |     |                |
| DYE DC BLUE #2 LAKE<br>ORAL; CAPSULE               | 000130201 | 2            |             | 04/21/87         | 600 |                |
| ORAL; TABLET, COATED                               |           | 1            |             |                  |     |                |
| DYE DC BLUE #6<br>ORAL; CAPSULE                    | 000482893 | 2            |             | 09/21/77         | 600 |                |
| DYE DC GREEN #3 LAKE<br>ORAL; CAPSULE              |           | 1            |             |                  |     |                |
| ORAL; TABLET, COATED                               |           | 1            |             |                  |     |                |
| DYE DC GREEN #5<br>ORAL; CAPSULE, SUSTAINED ACTION | 004403901 | 1            |             |                  |     |                |
| ORAL; SOLUTION                                     |           | 1            |             |                  |     |                |
| ORAL; SOLUTION, ELIXIR                             |           | 2            |             | 04/10/78         | 600 | 0.0009%        |
| ORAL; TABLET, COATED                               |           | 1            |             |                  |     |                |
| ORAL-21; TABLET                                    |           | 2            |             | 04/13/84         | 510 | 0.0024MG       |
| ORAL-28; TABLET                                    |           | 3            |             | 04/13/84         | 510 | 0.0024MG       |
| TOPICAL; EMULSION, CREAM                           |           | 1            |             |                  |     |                |
| TOPICAL; LOTION                                    |           | 1            |             |                  |     |                |
| DYE DC RED #19<br>ORAL; SUSPENSION                 | 000081889 | 1            |             |                  |     |                |
| DYE DC RED #21 LAKE<br>ORAL; CAPSULE               |           | 1            |             |                  |     |                |
| DYE DC RED #22<br>ORAL; CAPSULE                    | 000548265 | 9            |             | 09/11/92         | 530 |                |
| ORAL; CAPSULE, SUSTAINED ACTION                    |           | 1            |             |                  |     |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| DYE DC RED #27                                 | 002134158 | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 8            |             | 01/02/87         | 600 | 0.5UGM            |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| DYE DC RED #27 ALUMINUM LAKE                   |           | 4            |             | 03/11/88         | 600 |                   |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 11/21/77         | 600 |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                   |
| DYE DC RED #28                                 | 004618239 | 81           |             | 07/03/95         | 600 | 0.002MG           |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, COATED, SOFT GELATIN            |           | 3            |             | 10/05/95         | 180 |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, HARD GELATIN                    |           | 9            |             | 09/11/95         | 110 |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 2            |             | 04/22/68         | 520 | 0.014%            |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 08/31/90         | 520 |                   |
| DYE DC RED #3 LAKE                             |           | 2            |             | 08/06/79         | 600 | 0.2MG             |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                   |
| DYE DC RED #30                                 | 002379740 | 1            |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 16           |             | 04/27/95         | 600 | 0.0105MG - 0.93MG |
| ORAL; TABLET                                   |           | 3            |             | 12/20/82         | 600 |                   |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 4            |             | 12/29/92         | 120 |                   |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 2            |             | 12/30/91         | 600 |                   |
| ORAL-21; TABLET                                |           | 5            |             | 12/30/91         | 600 |                   |
| ORAL-28; TABLET                                |           | 26           |             | 01/31/95         | 600 | 0.0324MG - 3.0MG  |
| DYE DC RED #30 ALUMINUM LAKE                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 5            |             | 08/30/83         | 600 | 0.29GM            |
| ORAL; TABLET, FILM COATED                      | 1         |              |             |                  |     |                   |
| DYE DC RED #30 LAKE                            |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                   |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 6            |             | 10/30/92         | 600 | 0.04MG - 0.4MG    |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 2            |             | 11/05/81         | 600 |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET                                |           |              |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV      | POTENCY RANGE    |        |
|---------------------------------------|-----------|--------------|-------------|------------------|----------|------------------|--------|
| DYE DC RED #33                        | 003567666 | 28           |             | 03/03/96         | 110      | 0.0001MG         |        |
| ORAL; CAPSULE                         |           | 1            |             |                  |          |                  |        |
| ORAL; CAPSULE, HARD GELATIN           |           | 4            |             | 07/03/85         | 110      | 0.0013MG         |        |
| ORAL; CAPSULE, SUSTAINED ACTION       |           | 1            |             |                  |          |                  |        |
| ORAL; CONCENTRATE                     |           | 2            |             | 04/27/88         | 510      |                  |        |
| ORAL; SOLUTION                        |           | 7            |             | 12/16/83         | 600      |                  |        |
| ORAL; SOLUTION, ELIXIR                |           | 2            |             | 12/18/80         | 600      |                  |        |
| ORAL; SUSPENSION                      |           | 13           |             | 03/07/85         | 600      | 0.001848%        |        |
| ORAL; SYRUP                           |           | 8            |             | 06/16/88         | 110      | 0.007MG - 0.15MG |        |
| ORAL; TABLET                          |           | 1            |             |                  |          |                  |        |
| TOPICAL; SHAMPOO                      |           |              |             |                  |          |                  |        |
| DYE DC RED #33 LAKE                   |           |              | 3           |                  | 02/25/88 | 600              | 1.79MG |
| ORAL; CAPSULE                         |           |              | 3           |                  | 11/22/85 | 600              |        |
| ORAL; SYRUP                           |           |              |             |                  |          |                  |        |
| DYE DC RED #36                        |           | 3            |             | 09/07/77         | 110      | 0.01MG - 48.75MG |        |
| ORAL; TABLET                          |           | 1            |             |                  |          |                  |        |
| TOPICAL; EMULSION, CREAM              |           | 1            |             |                  |          |                  |        |
| TOPICAL; OINTMENT                     |           |              |             |                  |          |                  |        |
| DYE DC RED #39                        | 006371557 | 1            |             |                  |          |                  |        |
| TOPICAL; LOTION                       |           |              |             |                  |          |                  |        |
| DYE DC RED #4 LAKE                    |           | 1            |             |                  |          |                  |        |
| ORAL; CAPSULE                         |           |              |             |                  |          |                  |        |
| DYE DC RED #40 LAKE                   |           | 4            |             | 03/02/92         | 600      |                  |        |
| ORAL; CAPSULE                         |           | 1            |             |                  |          |                  |        |
| ORAL; CAPSULE, ENTERIC COATED PELLETS |           | 1            |             |                  |          |                  |        |
| ORAL; CAPSULE, SUSTAINED ACTION       |           | 1            |             |                  |          |                  |        |
| ORAL; SOLUTION, ELIXIR                |           | 1            |             |                  |          |                  |        |
| ORAL; TABLET                          |           | 4            |             | 01/31/95         | 600      |                  |        |
| ORAL; TABLET, COATED                  |           | 1            |             |                  |          |                  |        |
| RECTAL; SUPPOSITORY                   |           | 1            |             |                  |          |                  |        |
| DYE DC RED #6                         | 005858811 | 1            |             |                  |          |                  |        |
| ORAL; TABLET, COATED                  |           |              |             |                  |          |                  |        |
| DYE DC RED #6 LAKE                    |           | 2            |             | 03/01/90         | 180      | 0.4MG            |        |
| ORAL; TABLET                          |           |              |             |                  |          |                  |        |
| DYE DC RED #7                         | 005281049 | 10           |             | 12/21/93         | 600      | 0.16MG - 0.6MG   |        |
| ORAL; TABLET                          |           | 2            |             | 01/26/84         | 510      |                  |        |
| ORAL; TABLET, COATED                  |           | 1            |             |                  |          |                  |        |
| ORAL; TABLET, FILM COATED             |           | 1            |             |                  |          |                  |        |
| ORAL; TABLET, SUSTAINED ACTION        |           | 1            |             |                  |          |                  |        |
| DYE DC RED #7 CALCIUM LAKE            |           | 2            |             | 12/20/90         | 110      |                  |        |
| ORAL; CAPSULE                         |           | 1            |             |                  |          |                  |        |
| ORAL; CAPSULE, ENTERIC COATED PELLETS |           | 1            |             |                  |          |                  |        |
| ORAL; CAPSULE, HARD GELATIN           |           | 1            |             |                  |          |                  |        |
| ORAL; CAPSULE, SUSTAINED ACTION       |           | 14           |             | 12/21/93         | 600      |                  |        |
| ORAL; TABLET                          |           | 1            |             |                  |          |                  |        |
| ORAL; TABLET, COATED                  |           | 1            |             |                  |          |                  |        |
| ORAL; TABLET, FILM COATED             |           | 1            |             |                  |          |                  |        |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| DYE DC RED #7 CALCIUM LAKE<br>ORAL; TABLET, SUSTAINED ACTION |           | 2            |             | 01/16/85         | 600 |                    |
| DYE DC RED #7 LAKE<br>ORAL; TABLET                           |           | 4            |             | 01/25/88         | 600 | 0.02MG - 0.6MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                 |           | 1            |             |                  |     |                    |
| DYE DC RED LAKE<br>ORAL; TABLET                              |           | 6            |             | 09/25/95         | 600 | 0.009MG - 2.4MG    |
| DYE DC VIOLET #2 LAKE<br>ORAL; TABLET                        |           | 1            |             |                  |     |                    |
| DYE DC YELLOW<br>ORAL; CAPSULE                               |           | 3            |             | 07/31/92         | 600 |                    |
| DYE DC YELLOW #10<br>BUCCAL; GUM, CHEWING                    | 008004920 | 1            |             |                  |     |                    |
| DENTAL; GEL  |           | 1            |             |                  |     |                    |
| DENTAL; PASTE  |           | 1            |             |                  |     |                    |
| ORAL; CAPLET   |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE  |           | 169          |             | 08/31/95         | 600 | 2.0UGM             |
| ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GEL               |           | 2            |             | 01/29/93         | 600 |                    |
| ORAL; CAPSULE, COATED PELLETS                                |           | 2            |             | 06/30/92         | 600 |                    |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                        |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, HARD GELATIN                                  |           | 3            |             | 05/21/95         | 600 |                    |
| ORAL; CAPSULE, SOFT GELATIN                                  |           | 2            |             | 07/26/82         | 110 | 0.111MG            |
| ORAL; CAPSULE, SUSTAINED ACTION                              |           | 16           |             | 05/10/93         | 180 | 0.25MG             |
| ORAL; CONCENTRATE  |           | 3            |             | 01/30/92         | 600 | 0.0008% - 0.0014%  |
| ORAL; POWDER   |           | 2            |             | 12/05/88         | 510 | 0.00003%           |
| ORAL; SOLUTION   |           | 7            |             | 06/30/93         | 600 | 0.0005% - 0.005%   |
| ORAL; SOLUTION, ELIXIR                                       |           | 3            |             | 08/28/92         | 600 |                    |
| ORAL; SUSPENSION   |           | 9            |             | 06/16/95         | UNK | 0.00027% - 0.0015% |
| ORAL; SUSPENSION, SUSTAINED ACTION                           |           | 1            |             |                  |     |                    |
| ORAL; SYRUP  |           | 13           |             | 08/11/90         | UNK | 0.0028% - 0.0036%  |
| ORAL; TABLET   |           | 131          |             | 06/29/95         | 600 | 0.0035MG - 5.0MG   |
| ORAL; TABLET, COATED   |           | 8            |             | 04/26/78         | 600 | 2.5MG              |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                 |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                                    |           | 19           |             | 04/28/95         | 110 | 0.006MG - 0.068MG  |
| ORAL; TABLET, SUSTAINED ACTION                               |           | 8            |             | 11/08/93         | UNK | 0.071MG - 2.01MG   |
| ORAL-21; TABLET  |           | 6            |             | 12/30/91         | 600 | 0.02MG             |
| ORAL-28; TABLET  |           | 7            |             | 12/30/91         | 600 | 0.02MG - 0.06MG    |
| RECTAL; SUPPOSITORY  |           | 1            |             |                  |     |                    |
| SUBLINGUAL; TABLET   |           | 3            |             | 02/26/88         | 600 | 0.028MG - 0.23MG   |
| TOPICAL; EMULSION, CREAM                                     |           | 1            |             |                  |     |                    |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                    |
| TOPICAL; SHAMPOO   |           | 1            |             |                  |     |                    |
| DYE DC YELLOW #10 ALUMINUM LAKE<br>ORAL; CAPLET              |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE  |           | 7            |             | 08/15/94         | 180 |                    |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                        |           | 1            |             |                  |     |                    |
| ORAL; TABLET   |           | 72           |             | 10/11/95         | 600 | 0.008MG - 2.5MG    |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| DYE DC YELLOW #10 ALUMINUM LAKE                |           | 8            |             | 03/07/77         | 600 |                     |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 7            |             | 04/14/95         | 110 | 0.0075MG - 0.045MG  |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 03/31/81         | UNK |                     |
| ORAL; TABLET, REPEAT ACTION                    |           | 6            |             | 07/31/92         | 600 |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 2            |             | 01/29/87         | 600 | 0.096MG - 0.415MG   |
| ORAL-21; TABLET                                |           | 12           |             | 07/03/92         | 510 | 0.096MG - 0.415MG   |
| ORAL-28; TABLET                                |           |              |             |                  |     |                     |
| DYE DC YELLOW #10 HT LAKE                      |           | 5            |             | 06/13/88         | 600 | 0.1MG - 1.4MG       |
| ORAL; TABLET                                   |           |              |             |                  |     |                     |
| DYE DC YELLOW #10 LAKE                         |           | 1            |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 74           |             | 08/29/95         | 600 | 0.000289MG - 5.71MG |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 3            |             | 04/20/76         | 600 |                     |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 5            |             | 05/20/85         | 600 | 0.12GM              |
| ORAL; TABLET, FILM COATED                      |           | 3            |             | 07/29/88         | 110 | 0.18MG - 2.33MG     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| SUBLINGUAL; TABLET                             |           |              |             |                  |     |                     |
| DYE DC YELLOW #5 LAKE                          |           | 8            |             | 08/11/80         | 600 | 0.016MG - 2.69MG    |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           |              |             |                  |     |                     |
| DYE DC YELLOW #6                               |           | 3            |             | 12/28/90         | 600 |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 3            |             | 01/12/75         | 600 | 0.005MG             |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL-21; TABLET                                |           |              |             |                  |     |                     |
| DYE DC YELLOW #6 LAKE                          |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; SOLUTION                                 |           | 15           |             | 11/02/87         | 600 | 0.27UGM             |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                      |           |              |             |                  |     |                     |
| DYE FDC BLUE #1                                | 002650182 | 1            |             |                  |     |                     |
| DENTAL; PASTE                                  |           | 4            |             | 12/28/95         | 600 | 0.00005% - 0.0015%  |
| DENTAL; SOLUTION                               |           | 237          |             | 10/18/95         | 600 | 5.0UGM              |
| ORAL; CAPSULE                                  |           | 2            |             | 06/30/92         | 600 |                     |
| ORAL; CAPSULE, COATED PELLETS                  |           | 4            |             | 10/05/95         | 180 |                     |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 6            |             | 03/27/95         | 600 | 3.708MG             |
| ORAL; CAPSULE, HARD GELATIN                    |           | 3            |             | 03/08/94         | 180 |                     |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 28           |             | 09/11/95         | 110 | 0.019MG - 0.9MG     |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 2            |             | 04/23/79         | 600 |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 5            |             | 05/28/93         | 600 | 0.000075% - 0.75%   |
| ORAL; SOLUTION                                 |           | 2            |             | 04/29/92         | 600 |                     |
| ORAL; SOLUTION, ELIXIR                         |           | 2            |             | 02/12/86         | 520 | 0.005%              |
| ORAL; SUSPENSION                               |           | 16           |             | 12/23/88         | 600 |                     |
| ORAL; SYRUP                                    |           |              |             |                  |     |                     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| DYE FDC BLUE #1                                | 002650182 | 129          |             | 06/29/95         | 600 | 5.0UGM - 11.4UGM    |
| ORAL; TABLET                                   |           | 9            |             | 02/11/87         | 120 | 0.0052MG - 0.0085MG |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 10           |             | 10/31/91         | 180 | 0.51UGM             |
| ORAL; TABLET, FILM COATED                      |           | 6            |             | 11/08/93         | UNK | 0.03MG              |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 3            |             | 07/01/88         | 600 | 0.01MG - 0.05MG     |
| ORAL-21; TABLET                                |           | 6            |             | 07/01/88         | 600 | 0.01MG - 0.05MG     |
| ORAL-28; TABLET                                |           | 3            |             | 05/28/93         | 600 | 0.000075%           |
| RECTAL; SOLUTION                               |           | 1            |             |                  |     |                     |
| SUBLINGUAL; TABLET                             |           | 2            |             | 08/21/90         | UNK | 0.0036%             |
| TOPICAL; SHAMPOO                               |           | 1            |             |                  |     |                     |
| TOPICAL; SUSPENSION, SHAMPOO                   |           | 1            |             |                  |     |                     |
| TOPICAL; SWAB                                  |           | 1            |             |                  |     |                     |
| DYE FDC BLUE #1 ALUMINUM LAKE                  |           | 12           |             | 08/15/94         | 180 |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, HARD GELATIN                    |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                     |
| ORAL; SYRUP                                    |           | 114          |             | 12/29/95         | 600 | 0.001MG - 2.5MG     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 04/20/76         | 600 |                     |
| ORAL; TABLET, COATED                           |           | 2            |             | 05/15/90         | 600 |                     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 4            |             | 05/30/95         | 600 | 0.1MG - 0.2MG       |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                     |
| ORAL; TABLET, REPEAT ACTION                    |           | 4            |             | 07/29/88         | 110 | 0.009MG - 0.29MG    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| ORAL-28; TABLET                                |           | 11           |             | 08/31/88         | 600 | 0.012MG - 0.3MG     |
| DYE FDC BLUE #1 H.T. ALUMINUM LAKE             |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 35           |             | 08/29/95         | 600 | 0.00364MG - 2.675MG |
| DYE FDC BLUE #1 LAKE                           |           | 2            |             | 04/08/81         | 600 |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 2            |             | 12/30/94         | 510 | 0.045MG             |
| ORAL; TABLET, COATED                           |           | 2            |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                     |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                     |
| DYE FDC BLUE #10                               |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| DYE FDC BLUE #2                                | 000860220 | 15           |             | 10/18/95         | 600 | 0.012MG             |
| BUCCAL; TABLET                                 |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 2            |             | 05/05/95         | 550 |                     |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 3            |             | 02/21/92         | 110 | 2.1UGM              |
| ORAL; CAPSULE, HARD GELATIN                    |           | 75           |             | 06/29/95         | 600 | 0.0015MG - 20.016MG |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 10           |             | 02/25/92         | 600 | 24.12MG             |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET, COATED                           |           | 11           |             | 12/29/92         | 120 | 0.7MG               |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           |              |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                      |           |              |             |                  |     |                     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|---|-----------|--------------|-------------|------------------|-----|---------------------|
| DYE FDC BLUE #2<br>ORAL; TABLET, SUSTAINED ACTION       | 000860220 | 5            |             | 09/22/94         | 110 |                     |
| DYE FDC BLUE #2 LAKE<br>ORAL; CAPSULE                   | 012227859 | 11           |             | 08/15/96         | 180 |                     |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 1            |             |                  |     |                     |
| ORAL; TABLET  |           | 77           |             | 12/29/95         | 600 | 0.035MG - 6.0MG     |
| ORAL; TABLET, COATED                                    |           | 14           |             | 12/20/82         | 600 | 0.095MG - 0.1425MG  |
| ORAL; TABLET, FILM COATED                               |           | 9            |             | 06/23/95         | 530 | 0.015MG - 0.3MG     |
| ORAL; TABLET, REPEAT ACTION                             |           | 1            |             |                  |     |                     |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 7            |             | 01/04/87         | 600 | 0.02MG              |
| ORAL; TABLET, UNCOATED, TROCHE                          |           | 1            |             |                  |     |                     |
| ORAL-21; TABLET   |           | 3            |             | 07/05/92         | 510 | 0.1MG - 0.208MG     |
| ORAL-28; TABLET   |           | 12           |             | 11/17/95         | 510 | 0.0649MG - 0.208MG  |
| DYE FDC GREEN #3<br>DENTAL; GEL                         | 002353459 | 1            |             |                  |     |                     |
| ORAL; CAPSULE   |           | 45           |             | 05/03/95         | 520 | 0.003MG - 0.066MG   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                   |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, SOFT GELATIN                             |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 6            |             | 09/11/95         | 110 | 0.015MG             |
| ORAL; SOLUTION, ELIXIR                                  |           | 1            |             |                  |     |                     |
| ORAL; SYRUP   |           | 4            |             | 08/17/90         | UNK | 0.00032%            |
| ORAL; TABLET  |           | 6            |             | 09/15/83         | 600 | 0.0004MG - 10.0MG   |
| ORAL; TABLET, COATED                                    |           | 2            |             | 03/22/60         | 110 | 0.005MG             |
| RECTAL; SUPPOSITORY                                     |           | 1            |             |                  |     |                     |
| DYE FDC GREEN #6<br>ORAL; CAPSULE                       |           | 1            |             |                  |     |                     |
| DYE FDC RED #27 LAKE<br>ORAL; CAPSULE, SUSTAINED ACTION |           | 1            |             |                  |     |                     |
| ORAL; TABLET  |           | 3            |             | 06/19/85         | 600 | 0.06MG              |
| DYE FDC RED #28<br>ORAL; CAPSULE                        |           | 13           |             | 03/29/91         | 600 |                     |
| ORAL; POWDER, FOR RECONSTITUTION                        |           | 1            |             |                  |     |                     |
| DYE FDC RED #3<br>ORAL; CAPSULE                         | 016423680 | 84           |             | 10/18/95         | 600 | 0.00036MG - 0.333MG |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                   |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, HARD GELATIN                             |           | 2            |             | 05/28/67         | UNK |                     |
| ORAL; CAPSULE, SOFT GELATIN                             |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 11           |             | 01/26/89         | 600 | 0.037MG - 0.3MG     |
| ORAL; DROPS   |           | 2            |             | 12/18/80         | 600 |                     |
| ORAL; GRANULE   |           | 2            |             | 12/18/80         | 600 |                     |
| ORAL; POWDER, FOR RECONSTITUTION                        |           | 12           |             | 12/23/91         | 520 | 0.004% - 0.525%     |
| ORAL; SOLUTION, ELIXIR                                  |           | 1            |             |                  |     |                     |
| ORAL; SUSPENSION  |           | 2            |             | 09/23/74         | 520 |                     |
| ORAL; TABLET  |           | 44           |             | 08/31/90         | 520 | 2.5UGM              |
| ORAL; TABLET, COATED                                    |           | 4            |             | 08/16/85         | 120 | 0.005MG             |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED            |           | 1            |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                               |           | 2            |             | 09/28/77         | 600 |                     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV      | POTENCY RANGE     |                  |
|---|-----------|--------------|-------------|------------------|----------|-------------------|------------------|
| DYE FDC RED #3<br>ORAL; TABLET, SUSTAINED ACTION        | 016423680 | 2            |             | 08/30/84         | 110      |                   |                  |
| ORAL-28; TABLET   |           | 1            |             |                  |          |                   |                  |
| DYE FDC RED #3 LAKE<br>TOPICAL; SHAMPOO                 |           | 1            |             |                  |          |                   |                  |
| DYE FDC RED #3 LAKE<br>ORAL; TABLET                     |           | 13           |             | 11/10/88         | 600      | 0.006MG - 1.2MG   |                  |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 1            |             |                  |          |                   |                  |
| DYE FDC RED #3-ALUMINUM LAKE<br>ORAL; CAPSULE           | 012227780 | 1            |             |                  |          |                   |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 1            |             |                  |          |                   |                  |
| ORAL; GRANULE   |           | 1            |             |                  |          |                   |                  |
| ORAL; POWDER, FOR RECONSTITUTION                        |           | 1            |             |                  |          |                   |                  |
| ORAL; TABLET  |           | 32           |             |                  | 05/11/90 | 600               | 0.02MG - 8.0MG   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,          |           | 2            |             |                  | 10/21/80 | 520               | 0.126MG - 4.25MG |
| ORAL; TABLET, FILM COATED                               |           | 1            |             |                  |          |                   |                  |
| TOPICAL; SOLUTION                                       |           | 1            |             |                  |          |                   |                  |
| DYE FDC RED #30 LAKE<br>ORAL; CAPSULE, SUSTAINED ACTION |           |              | 1           |                  |          |                   |                  |
| ORAL; TABLET  |           | 4            |             |                  | 12/21/87 | 600               |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,          | 1         |              |             |                  |          |                   |                  |
| DYE FDC RED #33<br>ORAL; CAPSULE                        |           | 4            |             | 03/06/87         | 600      | 262.0MG           |                  |
| ORAL; SYRUP   |           | 5            |             | 09/17/93         | 530      | 0.002%            |                  |
| DYE FDC RED #40<br>BUCCAL; TABLET                       |           | 1            |             |                  |          |                   |                  |
| ORAL; CAPSULE   |           | 128          |             | 10/18/95         | 600      | 0.0074MG - 73.2MG |                  |
| ORAL; CAPSULE, COATED, SOFT GELATIN                     |           | 1            |             |                  |          |                   |                  |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                   |           | 2            |             | 10/05/95         | 180      |                   |                  |
| ORAL; CAPSULE, HARD GELATIN                             |           | 2            |             | 01/28/91         | 110      |                   |                  |
| ORAL; CAPSULE, SOFT GELATIN                             |           | 2            |             | 07/26/82         | 110      | 0.074MG           |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 17           |             | 09/11/95         | 110      | 0.029MG - 0.129MG |                  |
| ORAL; CONCENTRATE                                       |           | 3            |             | 11/30/94         | 600      | 0.0025% - 0.0075% |                  |
| ORAL; DROPS   |           | 2            |             | 05/25/95         | UNK      | 0.001%            |                  |
| ORAL; POWDER  |           | 1            |             |                  |          |                   |                  |
| ORAL; POWDER, FOR RECONSTITUTION                        |           | 31           |             | 10/19/95         | 520      | 0.00001% - 0.032% |                  |
| ORAL; SOLUTION  |           | 13           |             | 12/22/94         | 600      | 0.0004% - 0.0007% |                  |
| ORAL; SOLUTION, ELIXIR                                  |           | 14           |             | 10/27/92         | 600      | 0.0012% - 0.005%  |                  |
| ORAL; SUSPENSION  |           | 21           |             | 09/15/95         | 180      | 0.004% - 0.9%     |                  |
| ORAL; SYRUP   |           | 36           |             | 01/13/95         | 600      | 0.002% - 0.04%    |                  |
| ORAL; TABLET  |           | 60           |             | 10/17/95         | 600      | 0.55UGM           |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,          |           | 2            |             | 10/04/76         | 600      | 0.2MG             |                  |
| ORAL; TABLET, COATED                                    |           | 6            |             | 08/16/77         | 180      |                   |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED            |           | 2            |             | 10/26/84         | 120      | 0.043MG           |                  |
| ORAL; TABLET, FILM COATED                               |           | 8            |             | 02/25/94         | 600      | 0.028MG           |                  |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 3            |             | 05/14/85         | UNK      |                   |                  |
| SUBLINGUAL; TABLET                                      |           | 2            |             | 07/29/88         | 110      | 0.003MG           |                  |
| TOPICAL; SOLUTION                                       |           | 3            |             | 01/28/92         | 600      | 0.6%              |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| DYE FDC RED #40                                |           | 2            |             | 02/28/91         | 600 | 0.005%           |
| DYE FDC RED #40 LAKE                           |           | 1            |             |                  |     |                  |
| ORAL; CAPLET                                   |           | 9            |             | 08/15/94         | 100 |                  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 2            |             | 01/26/89         | 600 | 0.024MG - 0.05MG |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 12/03/86         | 000 |                  |
| ORAL; SOLUTION                                 |           | 2            |             | 12/16/83         | 600 |                  |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                  |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                  |
| ORAL; SYRUP                                    |           | 54           |             | 10/20/95         | 600 | 0.01MG - 9.6MG   |
| ORAL; TABLET                                   |           | 3            |             | 07/29/92         | 600 | 0.368MG - 0.44MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 3            |             | 04/08/81         | 600 |                  |
| ORAL; TABLET, COATED                           |           | 2            |             | 12/20/91         | UNK |                  |
| ORAL; TABLET, FILM COATED                      |           | 4            |             | 12/02/85         | 600 | 0.054MG          |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                  |
| SUBLINGUAL; TABLET                             |           | 1            |             |                  |     |                  |
| DYE FDC RED #7 LAKE                            |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 4            |             | 02/27/91         | 600 | 0.06MG           |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                      |           | 23           |             | 10/18/95         | 600 | 0.2785MG         |
| DYE FDC YELLOW #10                             |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 2            |             | 12/05/88         | 000 | 3.0%             |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 10/17/90         | 600 | 0.0015%          |
| ORAL; SOLUTION                                 |           | 4            |             | 11/22/85         | 600 |                  |
| ORAL; SUSPENSION                               |           | 18           |             | 03/25/94         | 000 | 0.07MG - 3.15MG  |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 3            |             | 02/02/87         | 600 |                  |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                      |           | 3            |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                  |
| DYE FDC YELLOW #10 LAKE                        |           | 3            |             | 08/04/86         | 600 |                  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 44           |             | 12/29/95         | 600 | 0.01MG - 3.6MG   |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                  |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                  |
| SUBLINGUAL; TABLET                             |           | 1            |             |                  |     |                  |
| DYE FDC YELLOW #5                              | 001934210 | 1            |             |                  |     |                  |
| BUCCAL/SUBLINGUAL; TABLET                      |           | 17           |             | 08/23/84         | 600 | 0.06MG - 72.58MG |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| DYE FDC YELLOW #5                              | 001934210 |              |             |                  |     |                    |
| ORAL; SOLUTION, ELIXIR                         |           | 2            |             | 02/08/79         | 600 | 0.00034%           |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                    |
| ORAL; SYRUP                                    |           | 2            |             | 11/14/78         | 600 | 0.002%             |
| ORAL; TABLET                                   |           | 70           |             | 06/16/88         | 110 | 0.00044%           |
| ORAL; TABLET, COATED                           |           | 5            |             | 02/28/74         | 110 | 0.003MG - 0.0086MG |
| ORAL; TABLET, FILM COATED                      |           | 3            |             | 04/08/77         | 120 | 0.221MG - 1.68MG   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                    |
| TOPICAL; SUSPENSION, SHAMPOO                   |           | 1            |             |                  |     |                    |
| VAGINAL; SUPPOSITORY                           |           | 1            |             |                  |     |                    |
| DYE FDC YELLOW #5 LAKE                         | 012227699 |              |             |                  |     |                    |
| ORAL; TABLET                                   |           | 26           |             | 03/12/79         | 600 | 0.007MG - 2.423MG  |
| ORAL; TABLET, COATED                           |           | 4            |             | 06/17/77         | 600 |                    |
| DYE FDC YELLOW #6                              | 002783940 |              |             |                  |     |                    |
| ORAL; CAPSULE                                  |           | 152          |             | 08/31/95         | 600 |                    |
| ORAL; CAPSULE, COATED PELLETS                  |           | 2            |             | 06/30/92         | 600 |                    |
| ORAL; CAPSULE, HARD GELATIN                    |           | 2            |             | 03/27/95         | 600 |                    |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 4            |             | 03/08/94         | 180 | 0.022MG            |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 15           |             | 04/25/95         | UNK | 0.01MG - 4.5MG     |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                    |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                    |
| ORAL; POWDER                                   |           | 1            |             |                  |     |                    |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 9            |             | 04/18/91         | 600 | 0.003% - 0.04%     |
| ORAL; SOLUTION                                 |           | 38           |             | 07/03/95         | 600 | 0.002% - 1.5%      |
| ORAL; SOLUTION, ELIXIR                         |           | 6            |             | 04/29/93         | 600 |                    |
| ORAL; SUSPENSION                               |           | 19           |             | 03/30/94         | 600 | 0.00012% - 0.0025% |
| ORAL; SUSPENSION, SUSTAINED ACTION             |           | 1            |             |                  |     |                    |
| ORAL; SYRUP                                    |           | 36           |             | 09/25/95         | 600 | 0.00063% - 0.008%  |
| ORAL; TABLET                                   |           | 245          |             | 06/29/95         | 600 | 0.33UGM - 6.7UGM   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 3            |             | 01/04/95         | 600 | 0.2MG              |
| ORAL; TABLET, COATED                           |           | 21           |             | 09/10/87         | 600 | 0.045MG - 0.23MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 2            |             | 03/10/83         | 120 |                    |
| ORAL; TABLET, DISPERSIBLE                      |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                      |           | 31           |             | 08/01/92         | 520 | 0.029MG - 0.9MG    |
| ORAL; TABLET, REPEAT ACTION                    |           | 1            |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 9            |             | 01/23/93         | 600 | 0.02MG - 1.06MG    |
| ORAL-21; TABLET                                |           | 5            |             | 02/28/92         | 600 | 0.02MG - 0.03MG    |
| ORAL-28; TABLET                                |           | 12           |             | 12/13/93         | 600 | 0.0015MG - 0.03MG  |
| RECTAL; SOLUTION                               |           | 7            |             | 07/03/95         | 600 | 0.0075%            |
| SUBLINGUAL; TABLET                             |           | 3            |             | 07/29/88         | 110 | 0.008MG - 0.02MG   |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                    |
| TOPICAL; SPONGE                                |           | 1            |             |                  |     |                    |
| DYE FDC YELLOW #6 HT LAKE                      |           |              |             |                  |     |                    |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| DYE FDC YELLOW #6 LAKE                         | 012227600 |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 10           |             | 12/31/92         | 600 | 0.385MG - 39.0MG  |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 5            |             | 01/26/89         | 600 | 0.029MG - 0.18MG  |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                   |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 173          |             | 12/29/95         | 600 | 0.006MG - 6.33MG  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                           |           | 15           |             | 04/08/81         | 600 | 0.005MG           |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                      |           | 11           |             | 05/31/95         | 600 | 0.034MG - 0.176MG |
| ORAL; TABLET, REPEAT ACTION                    |           | 2            |             | 03/31/81         | UNK |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 12           |             | 01/31/94         | 600 | 0.015MG - 0.8MG   |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET                                |           | 2            |             | 03/29/76         | 510 |                   |
| SUBLINGUAL; TABLET                             |           | 2            |             | 02/19/88         | 600 | 0.003MG - 0.4MG   |
| DYE GRAY #2982                                 |           |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| DYE GREEN                                      |           |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 2            |             | 09/10/80         | 600 | 0.1MG             |
| DYE GREEN LB-482                               |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 3            |             | 04/05/88         | 600 | 0.25MG - 1.27MG   |
| DYE GREEN LB-603                               |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| DYE GREEN LB-883                               |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| DYE GREEN PMS-579                              |           |              |             |                  |     |                   |
| ORAL; CAPSULE, SOFT GELATIN LIQUID-FILLED      |           | 1            |             |                  |     |                   |
| DYE GREEN PR-1333                              |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| DYE MINT GREEN                                 |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                   |
| DYE OCHRE 3506                                 |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |
| DYE ORANGE                                     |           |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                   |
| DYE PINK                                       |           |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| DYE PURPLE LB-562                              |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 2            |             | 02/10/95         | 600 | 0.3MG - 0.81MG    |
| DYE RED  |           |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 2            |             | 05/02/73         | 600 | 0.081MG           |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 3            |             | 02/05/91         | 600 |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| DYE RED COTOLENE-P<br>ORAL; TABLET  |           | 1            |             |                  |     |                  |
| DYE SWEDISH ORANGE #2191<br>ORAL; CAPSULE                                     |           | 1            |             |                  |     |                  |
| DYE TETRAROME ORANGE<br>ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,        |           | 1            |             |                  |     |                  |
| DYE WHITE<br>ORAL; TABLET, SUSTAINED ACTION                                   |           | 1            |             |                  |     |                  |
| DYE WHITE COATERIC YPA-6-7089<br>ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 3            |             | 05/15/90         | 600 | 0.002374GM       |
| DYE WHITE COTOLENE-P<br>ORAL; TABLET  |           | 2            |             | 07/15/86         | 600 | 10.35MG - 20.7MG |
| DYE WHITE TC-1032<br>ORAL; TABLET   |           | 1            |             |                  |     |                  |
| DYE YELLOW<br>ORAL; CAPSULE   |           | 1            |             |                  |     |                  |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                  |
| ORAL; SYRUP   |           | 1            |             |                  |     |                  |
| DYE YELLOW #10<br>ORAL; CAPSULE   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED   |           | 1            |             |                  |     |                  |
| DYE YELLOW #62<br>ORAL; CAPSULE   |           | 1            |             |                  |     |                  |
| DYE YELLOW LB 9706<br>ORAL; TABLET  |           | 2            |             | 12/10/86         | 600 | 0.04MG - 0.27MG  |
| DYE YELLOW OCHRE<br>ORAL; TABLET  | 001345262 | 2            |             | 10/15/86         | 180 | 0.024MG - 0.4MG  |
| EDAMINE<br>INTRAVENOUS; INJECTION   |           | 6            |             | 09/25/91         | 600 | 0.36% - 0.374%   |
| IV(INFUSION); INJECTION   |           | 5            |             | 05/30/85         | 600 | 0.3% - 0.379%    |
| ORAL; SOLUTION  |           | 2            |             | 08/19/83         | 600 | 0.2%             |
| EDETATE CALCIUM DISODIUM<br>CAUDAL BLOCK; INJECTION                           | 023411349 | 1            |             |                  |     |                  |
| EPIDURAL; INJECTION   |           | 2            |             | 10/03/77         | UNK | 0.01%            |
| IM - IV; INJECTION  |           | 1            |             |                  |     |                  |
| INTRA-ARTERIAL; INJECTION   |           | 5            |             | 05/10/95         | 160 | 0.01% - 0.048%   |
| INTRA-ARTERIAL; SOLUTION, INJECTION   |           | 1            |             |                  |     |                  |
| INTRA-ARTICULAR; INJECTION  |           | 1            |             |                  |     |                  |
| INTRACARDIAC; INJECTION   |           | 2            |             | 06/01/88         | 600 | 0.01%            |
| INTRADISCAL; INJECTION  |           | 1            |             |                  |     |                  |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION                                 |           | 1            |             |                  |     |                  |
| INTRAPERITONEAL; POWDER, FOR INJECTION SOLUTION                               |           | 1            |             |                  |     |                  |
| INTRATHECAL; INJECTABLE   |           | 1            |             |                  |     |                  |
| INTRATHECAL; INJECTION  |           | 3            |             | 06/30/89         | 160 | 0.01% - 0.039%   |
| INTRATHECAL; SOLUTION   |           | 1            |             |                  |     |                  |
| INTRAUTERINE; INJECTION   |           | 1            |             |                  |     |                  |
| INTRAVASCULAR; INJECTION  |           | 9            |             | 05/10/95         | 160 | 0.009% - 0.02%   |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| EDETATE CALCIUM DISODIUM                     | 023411349 |              |             |                  |     |                  |
| INTRAVASCULAR; SOLUTION                      |           | 1            |             |                  |     |                  |
| INTRAVENOUS; INJECTION                       |           | 17           |             | 05/10/95         | 160 | 0.01% - 0.048%   |
| INTRAVENOUS; SOLUTION                        |           | 1            |             |                  |     |                  |
| INTRAVESICAL; SOLUTION                       |           | 1            |             |                  |     |                  |
| IV(INFUSION); INJECTION                      |           | 2            |             | 04/01/77         | 160 | 0.01%            |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                  |
| IV(INFUSION); SOLUTION                       |           | 1            |             |                  |     |                  |
| NERVE BLOCK; INJECTION                       |           | 2            |             | 10/03/72         | UNK | 0.01%            |
| ORAL; CAPSULE                                |           | 29           |             | 12/20/95         | 520 |                  |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 4            |             | 02/14/94         | 600 |                  |
| ORAL; CONCENTRATE                            |           | 1            |             |                  |     |                  |
| ORAL; DROPS                                  |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION             |           | 2            |             | 01/06/75         | 600 |                  |
| ORAL; SOLUTION                               |           | 2            |             | 10/24/95         | 160 | 0.01%            |
| ORAL; SUSPENSION                             |           | 5            |             | 02/29/88         | 600 | 0.03%            |
| ORAL; TABLET                                 |           | 2            |             | 06/23/89         | 600 | 2.0MG - 4.0MG    |
| ORAL; TABLET, FILM COATED                    |           | 3            |             | 01/06/78         | 110 | 0.1MG - 0.4MG    |
| PERIARTICULAR; INJECTION                     |           | 1            |             |                  |     |                  |
| RECTAL; SOLUTION                             |           | 2            |             | 10/24/95         | 160 | 0.01%            |
| URETERAL; SOLUTION                           |           | 2            |             | 04/12/72         | 160 | 0.01% - 0.011%   |
| EDETATE DISODIUM                             | 006381926 |              |             |                  |     |                  |
| IM - IV - SC; INJECTION                      |           | 1            |             |                  |     |                  |
| IM - IV; INJECTION                           |           | 57           |             | 10/31/94         | 600 | 0.01% - 1.0%     |
| IM - IV; SOLUTION, INJECTION                 |           | 3            |             | 03/05/90         | 600 | 0.05%            |
| INHALATION; SOLUTION                         |           | 36           |             | 07/28/95         | 600 | 0.01% - 0.05%    |
| INTRA-ARTERIAL; INJECTION                    |           | 1            |             |                  |     |                  |
| INTRA-ARTICULAR; INJECTION                   |           | 9            |             | 05/24/82         | 600 | 0.01% - 0.05%    |
| INTRABURSAL; INJECTION                       |           | 2            |             | 03/03/65         | UNK | 0.01% - 0.05%    |
| INTRACARDIAC; INJECTION                      |           | 1            |             |                  |     |                  |
| INTRADERMAL; INJECTION                       |           | 1            |             |                  |     |                  |
| INTRALESIONAL; INJECTION                     |           | 7            |             | 06/19/80         | 600 | 0.01% - 0.05%    |
| INTRAMUSCULAR; INJECTION                     |           | 20           |             | 01/27/95         | 600 | 0.01% - 0.1%     |
| INTRAMUSCULAR; SOLUTION, INJECTION           |           | 1            |             |                  |     |                  |
| INTRASYNOVIAL; INJECTION                     |           | 3            |             | 03/01/77         | UNK | 0.05%            |
| INTRAUTERINE; SOLUTION                       |           | 1            |             |                  |     |                  |
| INTRAVASCULAR; INJECTION                     |           | 2            |             | 07/27/87         | 160 | 0.05%            |
| INTRAVENOUS; INJECTION                       |           | 27           |             | 01/27/95         | 600 | 0.005% - 0.2%    |
| INTRAVENOUS; SOLUTION                        |           | 3            |             | 04/17/78         | 160 |                  |
| IV(INFUSION); INJECTION                      |           | 20           |             | 07/07/94         | 110 | 0.00368% - 1.0%  |
| NASAL; SOLUTION                              |           | 1            |             |                  |     |                  |
| NASAL; SPRAY                                 |           | 1            |             |                  |     |                  |
| NASAL; SPRAY, METERED                        |           | 5            |             | 10/20/95         | UNK | 0.01%            |
| NERVE BLOCK; INJECTION                       |           | 8            |             | 01/22/85         | 600 | 0.0003% - 0.025% |
| OPHTHALMIC; GEL                              |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION                         |           | 69           |             | 10/31/95         | 600 | 0.01% - 0.1%     |
| OPHTHALMIC; SUSPENSION                       |           | 23           |             | 12/30/94         | UNK | 0.01% - 0.13%    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|----------------------------------|-----------|--------------|-------------|------------------|-----|------------------|
| EDETATE DISODIUM                 | 006381926 |              |             |                  |     |                  |
| ORAL; CAPSULE                    |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SOFT GELATIN      |           | 1            |             |                  |     |                  |
| ORAL; CONCENTRATE                |           | 9            |             | 06/30/92         | 600 | 0.01% - 0.25%    |
| ORAL; POWDER, FOR RECONSTITUTION |           | 5            |             | 05/23/88         | 600 | 0.036% - 0.06%   |
| ORAL; SOLUTION                   |           | 30           |             | 11/17/95         | 530 | 0.01% - 0.2%     |
| ORAL; SOLUTION, ELIXIR           |           | 3            |             | 05/17/78         | 600 | 0.00351%         |
| ORAL; SUSPENSION                 |           | 8            |             | 12/27/91         | 600 | 0.05% - 0.09%    |
| ORAL; SYRUP                      |           | 13           |             | 02/27/92         | 600 | 0.1%             |
| ORAL; TABLET                     |           | 18           |             | 06/02/89         | 600 | 0.0025MG - 4.0MG |
| ORAL; TABLET, COATED             |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED        |           | 3            |             | 02/02/87         | 600 | 1.0MG - 2.0MG    |
| OTIC; SOLUTION                   |           | 4            |             | 01/16/85         | 600 | 0.01%            |
| RECTAL; ENEMA                    |           | 1            |             |                  |     |                  |
| RECTAL; SOLUTION                 |           | 2            |             | 09/02/81         | 600 | 0.04%            |
| SOFT TISSUE; INJECTION           |           | 4            |             | 05/24/82         | 600 | 0.01% - 0.05%    |
| SUBCUTANEOUS; INJECTION          |           | 2            |             | 02/18/86         | 600 | 0.1%             |
| TOPICAL; EMULSION, CREAM         |           | 13           |             | 10/29/93         | UNK | 0.01% - 0.2%     |
| TOPICAL; GEL                     |           | 6            |             | 12/30/94         | 600 | 0.01% - 0.05%    |
| TOPICAL; LOTION                  |           | 2            |             | 12/07/92         | UNK | 0.01% - 0.1%     |
| TOPICAL; OINTMENT                |           | 1            |             |                  |     |                  |
| TOPICAL; SOLUTION                |           | 2            |             | 05/09/77         | UNK |                  |
| URETERAL; SOLUTION               |           | 1            |             |                  |     |                  |
| VAGINAL; EMULSION, CREAM         |           | 1            |             |                  |     |                  |
| VAGINAL; GEL                     |           | 1            |             |                  |     |                  |
| EDETATE DISODIUM, ANHYDROUS      | 000139333 |              |             |                  |     |                  |
| INTRAVENOUS; INJECTION           |           | 2            |             | 12/30/88         | 150 | 0.01% - 0.5%     |
| OPHTHALMIC; SOLUTION             |           | 1            |             |                  |     |                  |
| EDETATE SODIUM                   | 000064028 |              |             |                  |     |                  |
| IM - IV - SC; INJECTION          |           | 1            |             |                  |     |                  |
| IM - IV; INJECTION               |           | 1            |             |                  |     |                  |
| INHALATION; SOLUTION             |           | 2            |             | 07/27/88         | 600 | 0.02%            |
| INTRAMUSCULAR; INJECTION         |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION             |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SOFT GELATIN      |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM         |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION                  |           | 3            |             | 01/24/92         | 600 |                  |
| TOPICAL; SPONGE                  |           | 1            |             |                  |     |                  |
| EDETIC ACID                      | 000060004 |              |             |                  |     |                  |
| OTIC; SUSPENSION                 |           | 1            |             |                  |     |                  |
| RECTAL; SUPPOSITORY              |           | 2            |             | 08/31/92         | 600 |                  |
| TOPICAL; EMULSION, AEROSOL FOAM  |           | 1            |             |                  |     |                  |
| TOPICAL; SHAMPOO                 |           | 1            |             |                  |     |                  |
| EGG YOLK PHOSPHATIDES            |           |              |             |                  |     |                  |
| INTRAVENOUS; EMULSION, INJECTION |           | 1            |             | 06/18/93         | 120 | 1.2%             |
| INTRAVENOUS; INJECTION           |           | 3            |             | 05/28/93         | 510 | 1.2%             |
| IV(INFUSION); INJECTION          |           | 6            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| ENTSUFON SODIUM<br>TOPICAL; EMULSION                             | 002917944 | 1            |             |                  |     |                  |
| ESSENCE FRITZBRO ORANGE<br>ORAL; SUSPENSION                      |           | 1            |             |                  |     |                  |
| ESSENCE LEMON<br>ORAL; SYRUP                                     |           | 2            |             | 06/28/85         | UNK | 0.25%            |
| ESSENCE ORANGE<br>ORAL; SYRUP                                    |           | 1            |             |                  |     |                  |
| ETHER<br>ORAL; AEROSOL   | 000060297 | 1            |             |                  |     |                  |
| ETHER<br>ORAL; CAPSULE   |           | 1            |             |                  |     |                  |
| ETHYL ACETATE<br>ORAL; TABLET                                    | 000141786 | 1            |             |                  |     |                  |
| ETHYL ACETATE<br>ORAL; TABLET, SUSTAINED ACTION                  |           | 1            |             |                  |     |                  |
| ETHYL HEXANEDIOL<br>TOPICAL; SOLUTION                            | 001321342 | 1            |             |                  |     |                  |
| ETHYL MALTOL<br>ORAL; SOLUTION, ELIXIR                           | 004940118 | 3            |             | 10/27/92         | 600 |                  |
| ETHYL OLEATE<br>TRANSDERMAL; FILM, CONTROLLED RELEASE            | 000111626 | 1            |             |                  |     |                  |
| ETHYL VANILLIN<br>ORAL; CAPSULE                                  | 000121324 | 8            |             | 07/25/91         | 600 | 0.081MG - 0.31MG |
| ETHYL VANILLIN<br>ORAL; CAPSULE, COATED, SOFT GELATIN            |           | 1            |             |                  |     |                  |
| ETHYL VANILLIN<br>ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |     |                  |
| ETHYL VANILLIN<br>ORAL; CAPSULE, SUSTAINED ACTION                |           | 2            |             | 04/25/95         | UNK |                  |
| ETHYL VANILLIN<br>ORAL; SUSPENSION                               |           | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>ORAL; CAPSULE                                  | 009004573 | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>ORAL; CAPSULE, SUSTAINED ACTION                |           | 28           |             | 02/08/95         | UNK | 2.15MG - 18.16MG |
| ETHYLCELLULOSE<br>ORAL; GRANULE FOR RECONSTITUTION, CR           |           | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>ORAL; SUSPENSION, SUSTAINED ACTION             |           | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>ORAL; TABLET                                   |           | 105          |             | 11/05/92         | 600 | 0.06ML           |
| ETHYLCELLULOSE<br>ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 07/29/92         | 600 | 8.8MG            |
| ETHYLCELLULOSE<br>ORAL; TABLET, COATED                           |           | 4            |             | 08/16/85         | 120 | 0.1MG            |
| ETHYLCELLULOSE<br>ORAL; TABLET, FILM COATED                      |           | 36           |             | 05/31/91         | 600 | 0.04MG - 56.8MG  |
| ETHYLCELLULOSE<br>ORAL; TABLET, SUSTAINED ACTION                 |           | 18           |             | 01/25/93         | 600 | 1.0MG - 225.0MG  |
| ETHYLCELLULOSE<br>TOPICAL; LOTION                                |           | 1            |             |                  |     |                  |
| ETHYLCELLULOSE<br>VAGINAL; TABLET                                |           | 3            |             | 10/17/85         | 600 | 4.0MG - 50.0MG   |
| ETHYLENE<br>ORAL; CAPSULE  | 000074851 | 1            |             |                  |     |                  |
| ETHYLENE GLYCOL<br>ORAL; CAPSULE                                 | 000107211 | 2            |             | 04/21/87         | 600 |                  |
| ETHYLENE GLYCOL<br>ORAL; TABLET                                  |           | 1            |             |                  |     |                  |
| ETHYLENE GLYCOL<br>TOPICAL; EMULSION, AEROSOL FOAM               |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| ETHYLENE GLYCOL<br>TOPICAL; SUSPENSION, SHAMPOO   | 000107211 | 1            |             |                  |     |                   |
| ETHYLENE GLYCOL MONOETHYL ETHER<br>ORAL; CAPSULE  | 000110805 | 1            |             |                  |     |                   |
| ETHYLENE VINYL ACETATE COPOLYMER<br>INTRAUTERINE; SUPPOSITORY, INSERT, CONTROLLED RELEASE |           | 1            |             |                  |     |                   |
| OPHTHALMIC; DRUG DELIVERY SYSTEM  |           | 1            |             |                  |     |                   |
| OPHTHALMIC; SUPPOSITORY, INSERT, CONTROLLED RELEASE                                       |           | 1            |             |                  |     |                   |
| PERIODONTAL; FILM, CONTROLLED RELEASE   |           | 1            |             |                  |     |                   |
| TRANSDERMAL; FILM, CONTROLLED RELEASE   |           | 4            |             | 10/12/93         | 510 |                   |
| ETHYLENEDIAMINE DIHYDROCHLORIDE<br>TOPICAL; EMULSION, CREAM                               | 000333186 | 1            |             |                  |     |                   |
| ETHYL PARABEN<br>ORAL; POWDER, FOR RECONSTITUTION   | 000120478 | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM  |           | 1            |             |                  |     |                   |
| ETHYL PARABEN SODIUM<br>ORAL; CAPSULE, SOFT GELATIN                                       |           | 2            |             | 12/30/86         | 150 | 0.24MG - 1.004MG  |
| EUCALYPTOL<br>DENTAL; SOLUTION  | 000470826 | 1            |             |                  |     |                   |
| EUDRAGIT E 100<br>TRANSDERMAL; FILM, CONTROLLED RELEASE                                   |           | 1            |             |                  |     |                   |
| EUDRAGIT E 30 D<br>ORAL; TABLET   |           | 1            |             |                  |     |                   |
| EUDRAGIT L 30 D<br>ORAL; CAPSULE, SUSTAINED ACTION  |           | 3            |             | 01/04/95         | 600 | 0.7MG - 2.16MG    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED  |           | 3            |             | 11/30/95         | 600 | 25.5MG            |
| EUDRAGIT NE 30D<br>ORAL; CAPSULE, SUSTAINED ACTION  |           | 4            |             | 09/11/95         | 110 | 8.53MG - 36.173MG |
| EUDRAGIT RL 30 D<br>ORAL; CAPSULE, SUSTAINED ACTION                                       |           | 1            |             |                  |     |                   |
| EUDRAGIT RS 30 D<br>ORAL; CAPSULE, SUSTAINED ACTION                                       |           | 1            |             |                  |     |                   |
| ORAL; TABLET, CONTROLLED RELEASE  |           | 1            |             |                  |     |                   |
| EXAMETAZIME<br>INTRAVENOUS; INJECTION   | 100551631 | 1            |             |                  |     |                   |
| FAT, EDIBLE<br>RECTAL; SUPPOSITORY  |           | 1            |             |                  |     |                   |
| FATTY ACID ESTERS, SATURATED<br>RECTAL; SUPPOSITORY                                       |           | 1            |             |                  |     |                   |
| FATTY ACID PENTAERYTHRIOL ESTER<br>TOPICAL; OINTMENT                                      |           | 1            |             |                  |     |                   |
| FATTY ALCOHOL CITRATE<br>TOPICAL; OINTMENT  |           | 1            |             |                  |     |                   |
| FATTY ALCOHOLS<br>VAGINAL; EMULSION, CREAM  |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| FERRIC OXIDE                                   |           |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 7            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                      |           | 1            |             | 04/07/95         | 600 | 0.025MG - 4.56MG  |
| ORAL-28; TABLET                                |           | 2            |             |                  |     |                   |
| TOPICAL; LOTION                                |           | 1            |             | 12/14/92         | 510 |                   |
| FERRIC OXIDE, RED                              | 001309371 |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 16           |             | 07/30/93         | 600 | 0.034MG - 0.29MG  |
| ORAL; CAPSULE, HARD GELATIN                    |           | 2            |             | 12/30/93         | 120 |                   |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 2            |             | 11/22/95         | 150 | 0.0355MG - 2.28MG |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 2            |             | 11/30/93         | 600 |                   |
| ORAL; TABLET                                   |           | 30           |             | 11/30/95         | 510 | 0.0024MG - 13.0MG |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 2            |             | 01/31/92         | 180 | 0.02MG - 2.3MG    |
| ORAL; TABLET, FILM COATED                      |           | 7            |             | 04/28/95         | 180 | 0.0038MG - 0.21MG |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 4            |             | 06/01/94         | 110 | 0.75MG - 1.5MG    |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                   |
| FERROSO FERRIC OXIDE                           | 001317619 |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 46           |             | 10/18/95         | 600 | 0.082MG           |
| ORAL; CAPSULE, COATED, SOFT GELATIN            |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, HARD GELATIN                    |           | 2            |             | 05/03/95         | 530 |                   |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 2            |             | 07/14/95         | 530 | 0.105MG - 0.3MG   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 5            |             | 09/11/95         | 110 |                   |
| ORAL; TABLET                                   |           | 10           |             | 05/31/95         | 600 | 0.2MG - 149.0MG   |
| ORAL; TABLET, COATED                           |           | 2            |             | 02/27/97         | 120 |                   |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 06/20/94         | 600 | 0.2MG             |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                   |
| FIRMENICH 51.226/T                             |           |              |             |                  |     |                   |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                   |
| FLAVOR   |           |              |             |                  |     |                   |
| BUCCAL; GUM, CHEWING                           |           | 1            |             |                  |     |                   |
| DENTAL; SOLUTION                               |           | 1            |             |                  |     |                   |
| INHALATION; AEROSOL, METERED                   |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| ORAL; CONCENTRATE                              |           | 4            |             | 01/30/92         | 600 |                   |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                   |
| ORAL; GRANULE                                  |           | 2            |             | 05/20/88         | 600 |                   |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 9            |             | 04/04/79         | 520 |                   |
| ORAL; SOLUTION                                 |           | 16           |             | 10/31/93         | 600 |                   |
| ORAL; SOLUTION, ELIXIR                         |           | 6            |             | 04/29/93         | 600 |                   |
| ORAL; SUSPENSION                               |           | 7            |             | 06/16/95         | UNK | 0.04%             |
| ORAL; SYRUP                                    |           | 12           |             | 10/31/93         | 600 |                   |
| ORAL; TABLET                                   |           | 4            |             | 02/02/82         | 120 |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 3            |             | 12/14/81         | 120 |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|--|-----------|--------------|-------------|------------------|-----|---------------|
| FLAVOR   |           | 1            |             |                  |     |               |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |               |
| ORAL; TABLET, DISPERSIBLE                      |           | 1            |             |                  |     |               |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |               |
| RECTAL; SOLUTION                               |           | 2            |             | 05/28/93         | 600 |               |
| FLAVOR ANISE                                   |           | 2            |             | 01/21/92         | 600 |               |
| ORAL; SOLUTION                                 |           | 2            |             |                  |     |               |
| FLAVOR APPLE                                   | 008047914 | 1            |             |                  |     |               |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |               |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |               |
| FLAVOR APRICOT                                 |           | 1            |             |                  |     |               |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |               |
| FLAVOR APRICOT PEACH                           |           | 2            |             | 11/22/85         | 600 | 0.05%         |
| ORAL; SYRUP                                    |           | 2            |             | 12/05/88         | 600 | 0.3% - 1.0%   |
| FLAVOR APRICOT 24829                           |           | 2            |             |                  |     |               |
| ORAL; SOLUTION                                 |           | 2            |             |                  |     |               |
| FLAVOR AROMALOK 182608                         |           | 2            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |               |
| FLAVOR AROMALOK 262453                         |           | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |               |
| FLAVOR BANANA                                  | 000123922 | 2            |             | 07/14/81         | 520 |               |
| ORAL; GRANULE                                  |           | 4            |             | 10/19/95         | 520 |               |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |               |
| ORAL; SOLUTION                                 |           | 3            |             | 09/25/92         | 600 |               |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |               |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |               |
| FLAVOR BANANA S884                             |           | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |               |
| FLAVOR BANANA 71507                            |           | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |               |
| FLAVOR BANANA 74546                            |           | 1            |             |                  |     |               |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |               |
| FLAVOR BERRY CITRUS BLEND 9621                 |           | 1            |             |                  |     |               |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |               |
| FLAVOR BERRY CITRUS BLEND 9756                 |           | 1            |             |                  |     |               |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |               |
| FLAVOR BERRY CREAM                             |           | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |               |
| FLAVOR BITTERNESS MODIFIER 15555               |           | 1            |             |                  |     |               |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |               |
| FLAVOR BLACK CHERRY                            | 008010433 | 3            |             | 07/22/92         | 600 |               |
| ORAL; SYRUP                                    |           | 3            |             |                  |     |               |
| FLAVOR BLACK CURRANT                           |           | 4            |             | 04/18/84         | UNK |               |
| ORAL; SYRUP                                    |           | 4            |             |                  |     |               |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-------|--------------|-------------|------------------|-----|------------------|
| FLAVOR BLOOD ORANGE                            |       |              |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 2            |             | 04/18/91         | 600 | 0.4% - 0.8%      |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                  |
| FLAVOR BLOOD ORANGE SA                         |       |              |             |                  |     |                  |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                  |
| FLAVOR BLOOD ORANGE 51.226T                    |       |              |             |                  |     |                  |
| ORAL; SOLUTION, ELIXIR                         |       | 1            |             |                  |     |                  |
| FLAVOR BLUEBERRY                               |       |              |             |                  |     |                  |
| ORAL; CONCENTRATE                              |       | 1            |             |                  |     |                  |
| FLAVOR BUBBLE GUM                              |       |              |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |                  |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                  |
| FLAVOR BUTTER VANILLA                          |       |              |             |                  |     |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 1            |             |                  |     |                  |
| FLAVOR BUTTERMINT TOFFEE                       |       |              |             |                  |     |                  |
| ORAL; SUSPENSION                               |       | 1            |             |                  |     |                  |
| FLAVOR BUTTERMINT 24020                        |       |              |             |                  |     |                  |
| ORAL; CONCENTRATE                              |       | 2            |             | 12/16/85         | 600 | 0.125% - 0.25%   |
| FLAVOR BUTTERSCOTCH                            |       |              |             |                  |     |                  |
| ORAL; CONCENTRATE                              |       | 1            |             |                  |     |                  |
| ORAL; SOLUTION                                 |       | 2            |             | 07/10/87         | 600 |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 2            |             | 09/04/87         | 600 | 1.5MG - 13.0MG   |
| FLAVOR BUTTERSCOTCH F-1785                     |       |              |             |                  |     |                  |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                  |
| ORAL; SYRUP                                    |       | 2            |             | 06/07/85         | 600 |                  |
| FLAVOR CANDIED SUGAR 510155U                   |       |              |             |                  |     |                  |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                  |
| FLAVOR CARAMEL FRITZSCHE                       |       |              |             |                  |     |                  |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                  |
| FLAVOR CHERI-BERI PFC-8573                     |       |              |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 3            |             | 05/19/88         | 600 | 0.5%             |
| FLAVOR CHERI-BERI PFC-8580                     |       |              |             |                  |     |                  |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                  |
| FLAVOR CHERRY                                  |       |              |             |                  |     |                  |
| ORAL; CONCENTRATE                              |       | 1            |             |                  |     |                  |
| ORAL; DROPS                                    |       | 1            |             |                  |     |                  |
| ORAL; GRANULE                                  |       | 3            |             | 12/18/80         | 600 |                  |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 10           |             | 12/20/95         | 520 |                  |
| ORAL; SOLUTION                                 |       | 10           |             | 10/27/92         | 600 | 0.15%            |
| ORAL; SOLUTION, ELIXIR                         |       | 2            |             | 04/23/64         | UNK |                  |
| ORAL; SUSPENSION                               |       | 8            |             | 02/28/94         | 600 | 0.09% - 5.0%     |
| ORAL; SYRUP                                    |       | 10           |             | 02/27/92         | 600 | 0.000125% - 0.8% |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 3            |             | 09/11/95         | 600 | 4.5MG - 14.0MG   |
| FLAVOR CHERRY BURGUNDY 11650                   |       |              |             |                  |     |                  |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY | RANGE |
|--|-------|--------------|-------------|------------------|-----|---------|-------|
| FLAVOR CHERRY CREAM<br>ORAL; SUSPENSION                                  |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY E.P. MODIFIED 151<br>ORAL; CONCENTRATE                     |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY EP-3699<br>ORAL; POWDER, FOR RECONSTITUTION                |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY F-232<br>ORAL; SOLUTION                                    |       | 3            |             | 09/15/92         | 600 |         |       |
| ORAL; SUSPENSION   |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY FMC 8513<br>ORAL; SOLUTION                                 |       | 1            |             | 10/13/87         | 600 |         |       |
| ORAL; SYRUP  |       | 2            |             |                  |     |         |       |
| FLAVOR CHERRY IFF 13530912<br>ORAL; SOLUTION, ELIXIR                     |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY MARASCHINO S-3531<br>ORAL; SUSPENSION                      |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY MINT<br>ORAL; SYRUP  |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY N-2755<br>ORAL; SYRUP                                      |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY R-6556<br>ORAL; POWDER, FOR RECONSTITUTION                 |       | 2            |             | 02/13/87         | 600 | 0.05%   |       |
| FLAVOR CHERRY RASPBERRY<br>ORAL; SYRUP                                   |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY WL-1093<br>ORAL; SYRUP                                     |       | 2            |             | 12/23/88         | 600 |         |       |
| FLAVOR CHERRY WL-18022<br>ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY WL-4658<br>ORAL; SOLUTION                                  |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY 11539<br>ORAL; SUSPENSION                                  |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY 181612<br>ORAL; POWDER, FOR RECONSTITUTION                 |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY 3321<br>ORAL; SYRUP  |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY 338614<br>ORAL; SUSPENSION                                 |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY 349<br>ORAL; SOLUTION, ELIXIR                              |       | 1            |             |                  |     |         |       |
| ORAL; SUSPENSION   |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY 500910U<br>ORAL; SUSPENSION                                |       | 1            |             |                  |     |         |       |
| FLAVOR CHERRY 594 S.D.<br>ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 1            |             |                  |     |         |       |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                  | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|--|-------|--------------|-------------|------------------|-----|---------------|
| FLAVOR CHERRY-ANISE<br>ORAL; SOLUTION            |       | 1            |             |                  |     |               |
| FLAVOR CHERRY-ANISE PFC 9758<br>ORAL; SOLUTION   |       | 1            |             |                  |     |               |
| ORAL; SYRUP                                      |       | 1            |             |                  |     |               |
| FLAVOR CHOCOLATE<br>ORAL; SUSPENSION             |       | 1            |             |                  |     |               |
| ORAL; SYRUP                                      |       | 1            |             |                  |     |               |
| FLAVOR CHOCOLATE CREAM<br>ORAL; SYRUP            |       | 1            |             |                  |     |               |
| FLAVOR CHOCOLATE P727<br>ORAL; SOLUTION          |       | 1            |             |                  |     |               |
| FLAVOR CITRUS<br>ORAL; CONCENTRATE               |       | 1            |             |                  |     |               |
| FLAVOR CITRUS MINT<br>ORAL; SYRUP                |       | 1            |             |                  |     |               |
| FLAVOR CITRUS-VANILLA<br>ORAL; SUSPENSION        |       | 1            |             |                  |     |               |
| FLAVOR COCOA<br>ORAL; SYRUP                      |       | 1            |             |                  |     |               |
| FLAVOR COCONUT CUSTARD<br>ORAL; SUSPENSION       |       | 2            |             | 01/26/84         | 600 | 0.0001%       |
| FLAVOR COLA FMC 15740<br>ORAL; SYRUP             |       | 1            |             |                  |     |               |
| FLAVOR COUGH SYRUP 110257<br>ORAL; SOLUTION      |       | 1            |             |                  |     |               |
| FLAVOR CREAM<br>ORAL; CONCENTRATE                |       | 1            |             |                  |     |               |
| ORAL; GRANULE                                    |       | 2            |             | 03/30/87         | 520 |               |
| ORAL; POWDER, FOR RECONSTITUTION                 |       | 1            |             |                  |     |               |
| ORAL; SUSPENSION                                 |       | 2            |             | 10/17/90         | 600 |               |
| FLAVOR CREME DE MENTHE<br>ORAL; SOLUTION         |       | 4            |             | 05/15/87         | 600 | 0.3%          |
| FLAVOR CREME DE MENTHE 14677<br>ORAL; SOLUTION   |       | 1            |             |                  |     |               |
| ORAL; SUSPENSION                                 |       | 1            |             |                  |     |               |
| FLAVOR CREME DE VANILLA 28156<br>ORAL; DROPS     |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION                 |       | 1            |             |                  |     |               |
| ORAL; SUSPENSION                                 |       | 1            |             |                  |     |               |
| FLAVOR CURACAO 50.397A<br>ORAL; SOLUTION, ELIXIR |       | 1            |             |                  |     |               |
| FLAVOR CUSTARD<br>ORAL; CONCENTRATE              |       | 1            |             |                  |     |               |
| ORAL; SUSPENSION                                 |       | 2            |             | 11/21/80         | 600 |               |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|--|-------|--------------|-------------|------------------|-----|---------------|
| FLAVOR CUSTARD 52.940/A FIR<br>ORAL; SOLUTION                          |       | 1            |             |                  |     |               |
| FLAVOR DF-119<br>DENTAL; PASTE   |       | 1            |             |                  |     |               |
| FLAVOR DF-1530<br>DENTAL; GEL  |       | 1            |             |                  |     |               |
| FLAVOR E-472<br>ORAL; CONCENTRATE                                      |       | 1            |             |                  |     |               |
| FLAVOR ENHANCER<br>DENTAL; PASTE                                       |       | 1            |             |                  |     |               |
| FLAVOR F-5397A<br>ORAL; CONCENTRATE                                    |       | 2            |             | 04/27/83         | 600 | 0.008% - 8.0% |
| FLAVOR FELTON 6-R-9<br>ORAL; SYRUP                                     |       | 1            |             |                  |     |               |
| FLAVOR FIG<br>ORAL; SOLUTION   |       | 2            |             | 06/20/79         | 180 | 0.1%          |
| FLAVOR FRITZSCHE<br>RECTAL; SOLUTION                                   |       | 1            |             |                  |     |               |
| FLAVOR FRITZSCHE<br>ORAL; SYRUP  |       | 2            |             | 03/22/85         | 600 |               |
| FLAVOR FRITZSCHE 21028-D<br>ORAL; SYRUP                                |       | 1            |             |                  |     |               |
| FLAVOR FRITZSCHE 75021<br>ORAL; SYRUP                                  |       | 1            |             |                  |     |               |
| FLAVOR FRUIT GUM 912<br>ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 1            |             |                  |     |               |
| FLAVOR FRUIT MINT 75588<br>ORAL; SUSPENSION                            |       | 1            |             |                  |     |               |
| FLAVOR FRUIT PUNCH<br>ORAL; GRANULE, FOR RECONSTITUTION                |       | 1            |             |                  |     |               |
| FLAVOR FRUIT PUNCH #28140<br>ORAL; SUSPENSION                          |       | 1            |             |                  |     |               |
| FLAVOR FRUIT PUNCH 14761FM<br>ORAL; SUSPENSION                         |       | 1            |             |                  |     |               |
| FLAVOR FRUIT PUNCH #28140<br>ORAL; POWDER, FOR RECONSTITUTION          |       | 1            |             |                  |     |               |
| FLAVOR FRUIT 01-10428<br>ORAL; CONCENTRATE                             |       | 1            |             |                  |     |               |
| FLAVOR FRUIT 84.6422<br>BUCCAL; GUM, CHEWING                           |       | 1            |             |                  |     |               |
| FLAVOR FRUITS<br>ORAL; CONCENTRATE                                     |       | 1            |             |                  |     |               |
| ORAL; SOLUTION, ELIXIR   |       | 1            |             |                  |     |               |
| ORAL; SYRUP  |       | 1            |             |                  |     |               |
| FLAVOR GRAPE<br>ORAL; GRANULE  |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION                                       |       | 1            |             |                  |     |               |
| ORAL; SYRUP  |       | 2            |             | 07/03/86         | 600 | 0.05%         |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|--|-----------|--------------|-------------|------------------|-----|---------------|
| FLAVOR GRAPE NECTOR PFC 8599<br>ORAL; SYRUP                  |           | 2            |             | 01/17/89         | 600 |               |
| FLAVOR GRAPE 13403873<br>ORAL; SUSPENSION                    |           | 1            |             |                  |     |               |
| FLAVOR GRAPEFRUIT<br>ORAL; AEROSOL SPRAY                     |           | 1            |             |                  |     | .27%          |
| FLAVOR GRENADINE<br>ORAL; SUSPENSION                         |           | 1            |             |                  |     |               |
| FLAVOR GUARANA<br>ORAL; POWDER, FOR RECONSTITUTION           |           | 2            |             | 03/27/78         | 600 | 0.12% - 0.16% |
| ORAL; SOLUTION, ELIXIR                                       |           | 1            |             |                  |     |               |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |               |
| FLAVOR GUARANA FMC-15417<br>ORAL; POWDER, FOR RECONSTITUTION |           | 1            |             |                  |     |               |
| FLAVOR HAVERSTROO ZD 49284<br>BUCCAL; GUM, CHEWING           |           | 1            |             |                  |     |               |
| FLAVOR HERB ALPINE<br>DENTAL; SOLUTION                       |           | 1            |             |                  |     |               |
| FLAVOR KOLA<br>ORAL; SUSPENSION                              |           | 1            |             |                  |     |               |
| FLAVOR LEMON<br>ORAL; POWDER, FOR RECONSTITUTION             | 008020197 | 1            |             |                  |     |               |
| ORAL; SOLUTION   |           | 2            |             | 08/30/82         | 600 | 0.003% - 3.0% |
| ORAL; SUSPENSION   |           | 2            |             | 06/03/59         | 120 | 0.116%        |
| FLAVOR LEMON CREAM<br>ORAL; GRANULE, FOR RECONSTITUTION      |           | 1            |             |                  |     |               |
| FLAVOR LEMON LIME<br>ORAL; SUSPENSION                        |           | 1            |             |                  |     |               |
| FLAVOR LEMON MINT FRITZSCHE 54369<br>ORAL; SYRUP             |           | 1            |             |                  |     |               |
| FLAVOR LEMON VANILLA<br>ORAL; SOLUTION                       |           | 1            |             |                  |     |               |
| RECTAL; SOLUTION   |           | 1            |             |                  |     |               |
| FLAVOR LEMON 812<br>ORAL; SYRUP                              |           | 1            |             |                  |     |               |
| FLAVOR LICORICE<br>ORAL; SUSPENSION                          |           | 1            |             |                  |     |               |
| ORAL; SYRUP  |           | 1            |             |                  |     |               |
| FLAVOR LIME<br>ORAL; SOLUTION, ELIXIR                        |           | 2            |             | 04/07/89         | 600 |               |
| ORAL; SYRUP  |           | 1            |             |                  |     |               |
| FLAVOR MAFCO-MAGNASWEET 180<br>ORAL; SOLUTION                |           | 1            |             |                  |     |               |
| FLAVOR MAQUE TREE 377(BUSH)<br>ORAL; SUSPENSION              |           | 1            |             |                  |     |               |

## INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| FLAVOR MCP LEMON DURAMONE 4409A<br>ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                   |
| FLAVOR MCP LIME DURAMONE 6419<br>ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,   |           | 1            |             |                  |     |                   |
| FLAVOR MINT<br>ORAL; SOLUTION   |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION, ELIXIR  |           | 2            |             | 04/07/89         | 600 |                   |
| ORAL; SUSPENSION  |           | 3            |             | 10/10/85         | UNK | 0.206%            |
| FLAVOR ORANGE<br>ORAL; POWDER   | 008050326 | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION  |           | 2            |             | 12/23/93         | 530 | 0.116%            |
| ORAL; SOLUTION  |           | 3            |             | 10/02/87         | 600 | 0.5%              |
| ORAL; SOLUTION, ELIXIR  |           | 2            |             | 01/25/84         | 600 | 0.025%            |
| ORAL; SUSPENSION  |           | 1            |             | 03/30/94         | 600 | 0.000125% - 0.04% |
| ORAL; SYRUP   |           | 4            |             | 06/10/87         | UNK | 0.4%              |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,<br>SUBLINGUAL; TABLET              |           | 1            |             |                  |     |                   |
| FLAVOR ORANGE #7679<br>ORAL; SYRUP  |           | 1            |             |                  |     |                   |
| FLAVOR ORANGE BANANA<br>ORAL; POWDER, FOR RECONSTITUTION                          |           | 2            |             | 04/18/91         | 600 | 0.2% - 0.4%       |
| FLAVOR ORANGE BANANA WL-18093<br>ORAL; POWDER, FOR RECONSTITUTION                 |           | 1            |             |                  |     |                   |
| FLAVOR ORANGE NATURAL & ARTIFICIAL<br>ORAL; POWDER, FOR RECONSTITUTION            |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                                    |           | 1            |             |                  |     |                   |
| FLAVOR ORANGE TERPENELESS<br>ORAL; POWDER, FOR RECONSTITUTION                     |           | 1            |             |                  |     |                   |
| FLAVOR ORANGE 13334<br>ORAL; SOLUTION   |           | 1            |             |                  |     |                   |
| FLAVOR ORANGE-LEMON TERPENELESS<br>ORAL; SUSPENSION                               |           | 1            |             |                  |     |                   |
| ORAL; SYRUP   |           | 1            |             |                  |     |                   |
| FLAVOR ORBIT SERENE 20340<br>ORAL; SOLUTION                                       |           | 1            |             |                  |     |                   |
| FLAVOR PASSION FRUIT<br>ORAL; CONCENTRATE   |           | 1            |             |                  |     |                   |
| ORAL; SYRUP   |           | 1            |             |                  |     |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                                    |           | 1            |             |                  |     |                   |
| FLAVOR PEACH<br>ORAL; CONCENTRATE   |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION  |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|--|-------|--------------|-------------|------------------|-----|----------------|
| FLAVOR PEACH MINT FRITZSCHE 106109             |       | 1            |             |                  |     |                |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                |
| FLAVOR PEACH PINEAPPLE                         |       | 1            |             |                  |     |                |
| ORAL; SUSPENSION                               |       | 1            |             |                  |     |                |
| ORAL; SUSPENSION, SUSTAINED ACTION             |       | 1            |             |                  |     |                |
| FLAVOR PEACH PINEAPPLE FMC 14258               |       | 1            |             |                  |     |                |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                |
| FLAVOR PEACH 13503584                          |       | 2            |             | 06/11/85         | UNK |                |
| ORAL; SOLUTION                                 |       | 2            |             |                  |     |                |
| FLAVOR PEPPERMINT                              |       | 1            |             |                  |     |                |
| DENTAL; SOLUTION                               |       | 1            |             |                  |     |                |
| ORAL; CONCENTRATE                              |       | 1            |             |                  |     |                |
| ORAL; SUSPENSION                               |       | 1            |             |                  |     |                |
| ORAL; SYRUP                                    |       | 4            |             | 10/28/94         | 600 | 0.5%           |
| ORAL; TABLET                                   |       | 8            |             | 07/02/87         | 600 | 2.5MG - 10.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 2            |             | 10/21/80         | 520 | 0.45MG - 9.0MG |
| ORAL; TABLET, FILM COATED                      |       | 1            |             |                  |     |                |
| SUBLINGUAL; TABLET                             |       | 2            |             | 06/08/84         | 600 | 1.0MG - 1.5MG  |
| FLAVOR PEPPERMINT STICK FMC 16170              |       | 2            |             | 12/16/85         | 600 | 0.125% - 0.25% |
| ORAL; CONCENTRATE                              |       | 2            |             |                  |     |                |
| FLAVOR PEPPERMINT 517                          |       | 1            |             |                  |     |                |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |                |
| FLAVOR PEPPERMINT, NATURAL SPRAYLENE           |       | 1            |             |                  |     |                |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                |
| FLAVOR PINEAPPLE                               |       | 5            |             | 04/28/95         | 600 |                |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |                |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                |
| ORAL; SUSPENSION                               |       | 3            |             | 03/30/94         | 600 | 0.01% - 0.02%  |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                |
| FLAVOR PINEAPPLE 182661                        |       | 1            |             |                  |     |                |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |                |
| FLAVOR PINEAPPLE-COCONUT                       |       | 1            |             |                  |     |                |
| ORAL; SUSPENSION                               |       | 1            |             |                  |     |                |
| FLAVOR RASPBERRY                               |       | 1            |             |                  |     |                |
| ORAL; CONCENTRATE                              |       | 2            |             |                  |     |                |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |                |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |                |
| ORAL; SOLUTION, ELIXIR                         |       | 1            |             |                  |     |                |
| ORAL; SUSPENSION                               |       | 5            |             | 12/18/89         | UNK | 0.1415% - 7.5% |
| ORAL; SYRUP                                    |       | 15           |             | 01/13/95         | 600 | 0.2%           |
| ORAL; TABLET, UNCOATED, TROCHE                 |       | 1            |             |                  |     |                |
| FLAVOR RASPBERRY A11693                        |       | 1            |             |                  |     |                |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                |
| FLAVOR RASPBERRY F-1784                        |       | 1            |             |                  |     |                |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|--|-------|--------------|-------------|------------------|-----|---------------|
| FLAVOR RASPBERRY F-1840                        |       | 1            |             |                  |     |               |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |               |
| FLAVOR RASPBERRY F-6887-S                      |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |               |
| FLAVOR RASPBERRY PFC-8407                      |       | 2            |             | 12/16/85         | 600 | 0.25% - 0.5%  |
| ORAL; CONCENTRATE                              |       | 2            |             |                  |     |               |
| FLAVOR RASPBERRY POLAK 5000064                 |       | 1            |             |                  |     |               |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |               |
| FLAVOR RASPBERRY 262085                        |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |               |
| FLAVOR RASPBERRY 28106                         |       | 1            |             |                  |     |               |
| ORAL; DROPS                                    |       | 1            |             |                  |     |               |
| ORAL; SUSPENSION                               |       | 1            |             |                  |     |               |
| FLAVOR RASPBERRY 954                           |       | 1            |             |                  |     |               |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 1            |             |                  |     |               |
| FLAVOR REFRACHESMENT FD-8027D                  |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |               |
| FLAVOR RHODIA PHARMACEUTICAL #RF 451           |       | 1            |             |                  |     |               |
| TOPICAL; SOLUTION                              |       | 1            |             |                  |     |               |
| FLAVOR ROOT BEER                               |       | 1            |             |                  |     |               |
| ORAL; CONCENTRATE                              |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |               |
| FLAVOR SHERRY                                  |       | 1            |             |                  |     |               |
| ORAL; SOLUTION, ELIXIR                         |       | 1            |             |                  |     |               |
| FLAVOR SPEARMINT                               |       | 1            |             |                  |     |               |
| ORAL; SOLUTION                                 |       | 1            |             |                  |     |               |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |               |
| TOPICAL; OINTMENT                              |       | 2            |             | 08/17/81         | 600 | 0.3% - 1.0%   |
| FLAVOR STRAWBERRY                              |       | 1            |             |                  |     |               |
| ORAL; CONCENTRATE                              |       | 1            |             |                  |     |               |
| ORAL; GRANULE                                  |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 14           |             | 04/28/95         | 600 | 0.04% - 1.0%  |
| ORAL; SOLUTION                                 |       | 2            |             | 11/17/95         | 530 | 0.08% - 0.3%  |
| ORAL; SYRUP                                    |       | 7            |             | 04/29/93         | 600 | 0.05%         |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 2            |             | 12/11/85         | 600 | 2.0MG - 2.8MG |
| FLAVOR STRAWBERRY F-5665                       |       | 1            |             |                  |     |               |
| ORAL; CONCENTRATE                              |       | 1            |             |                  |     |               |
| FLAVOR STRAWBERRY F-5930-A                     |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |               |
| FLAVOR STRAWBERRY F21204                       |       | 1            |             |                  |     |               |
| ORAL; SYRUP                                    |       | 1            |             |                  |     |               |
| FLAVOR STRAWBERRY GUARANA 586.997/APO5.51      |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |               |
| FLAVOR STRAWBERRY MICROSEAL                    |       | 1            |             |                  |     |               |
| ORAL; POWDER, FOR RECONSTITUTION               |       | 1            |             |                  |     |               |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-------|--------------|-------------|------------------|-----|-------------------|
| FLAVOR STRAWBERRY PFC-9626<br>ORAL; SYRUP                              |       | 1            |             |                  |     |                   |
| FLAVOR STRAWBERRY WL-16650<br>ORAL; POWDER, FOR RECONSTITUTION         |       | 1            |             |                  |     |                   |
| FLAVOR STRAWBERRY 133.5655<br>ORAL; GRANULE                            |       | 1            |             |                  |     |                   |
| FLAVOR STRAWBERRY 14953<br>ORAL; SOLUTION                              |       | 1            |             |                  |     |                   |
| FLAVOR STRAWBERRY 52312/AP<br>ORAL; POWDER, FOR RECONSTITUTION         |       | 2            |             | 05/23/88         | 600 | 0.09334% - 93.34% |
| FLAVOR STRAWBERRY 55058<br>ORAL; SYRUP                                 |       | 1            |             |                  |     |                   |
| FLAVOR STRAWBERRY 5951<br>ORAL; DROPS                                  |       | 1            |             |                  |     |                   |
| FLAVOR STRAWBERRY 9843<br>ORAL; SUSPENSION                             |       | 1            |             |                  |     |                   |
| FLAVOR STRAWBERRY 9843<br>ORAL; SYRUP                                  |       | 1            |             |                  |     |                   |
| FLAVOR SWEET<br>ORAL; SUSPENSION                                       |       | 1            |             |                  |     |                   |
| FLAVOR SWEET TONE 28837<br>ORAL; POWDER, FOR RECONSTITUTION            |       | 1            |             |                  |     |                   |
| FLAVOR TANGERINE<br>ORAL; SOLUTION                                     |       | 1            |             |                  |     |                   |
| FLAVOR TANGERINE FRITZSCHE 51465<br>ORAL; SYRUP                        |       | 1            |             |                  |     |                   |
| FLAVOR TETRAROME<br>ORAL; SUSPENSION                                   |       | 1            |             |                  |     |                   |
| FLAVOR TPF 135<br>ORAL; SUSPENSION                                     |       | 1            |             |                  |     |                   |
| FLAVOR TPF 143<br>ORAL; SUSPENSION                                     |       | 1            |             |                  |     |                   |
| FLAVOR TROPICAL FRUIT PUNCH N&A 50432<br>ORAL; SYRUP                   |       | 1            |             |                  |     |                   |
| FLAVOR TUTTI FRUTTI<br>ORAL; POWDER, FOR RECONSTITUTION                |       | 2            |             | 08/14/80         | 600 | 0.06%             |
| FLAVOR TUTTI FRUTTI 24093FM<br>ORAL; SYRUP                             |       | 1            |             |                  |     |                   |
| FLAVOR TUTTI FRUTTI 51.880/AP05.51<br>ORAL; POWDER, FOR RECONSTITUTION |       | 1            |             |                  |     |                   |
| FLAVOR TUTTI FRUTTI 51.880/AP05.51<br>ORAL; SUSPENSION                 |       | 1            |             |                  |     |                   |
| FLAVOR VANILLA<br>ORAL; POWDER, FOR RECONSTITUTION                     |       | 2            |             | 08/06/84         | 520 | 0.06%             |
| ORAL; SOLUTION   |       | 3            |             | 06/25/93         | 600 |                   |
| ORAL; SUSPENSION   |       | 3            |             | 12/18/89         | UNK | 5.0%              |
| ORAL; SYRUP  |       | 1            |             |                  |     |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                         |       | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                    | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| FLAVOR VANILLA<br>RECTAL; SOLUTION                                 |           | 1            |             |                  |     |                  |
| TOPICAL; PASTE   |           | 1            |             |                  |     |                  |
| FLAVOR VANILLA BANANA<br>ORAL; CONCENTRATE                         |           | 1            |             |                  |     |                  |
| FLAVOR VANILLA CREME<br>ORAL; SOLUTION                             |           | 2            |             | 12/03/86         | 600 |                  |
| ORAL; SYRUP  |           | 1            |             |                  |     |                  |
| FLAVOR VERALOCK BUBBLE GUM<br>ORAL; POWDER, FOR RECONSTITUTION     |           | 1            |             |                  |     |                  |
| FLAVOR WILD CHERRY<br>ORAL; POWDER, FOR RECONSTITUTION             |           | 3            |             | 09/15/80         | 600 | 0.7408% - 1.0%   |
| ORAL; SOLUTION   |           | 3            |             | 09/30/92         | 600 |                  |
| ORAL; SUSPENSION   |           | 5            |             | 06/18/87         | 600 | 0.1%             |
| ORAL; SYRUP  |           | 3            |             | 07/26/88         | UNK | 0.04% - 0.1453%  |
| RECTAL; SUSPENSION   |           | 2            |             | 11/17/86         | 600 |                  |
| FLAVOR WILD CHERRY NV-101-1489<br>ORAL; POWDER, FOR RECONSTITUTION |           | 2            |             | 02/13/87         | 600 | 0.05%            |
| FLAVOR WILD CHERRY PFC-14783<br>ORAL; SYRUP                        |           | 2            |             | 12/22/88         | 600 |                  |
| FLAVOR WILDCHERRY 7598<br>ORAL; SYRUP                              |           | 1            |             |                  |     |                  |
| FLAVOR WINTERGREEN<br>ORAL; POWDER, FOR RECONSTITUTION             |           | 1            |             |                  |     |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                     |           | 1            |             |                  |     |                  |
| FLAVOR WINTERGREEN PFC 8421<br>ORAL; SOLUTION                      |           | 1            |             |                  |     |                  |
| FLAVOR 57000 IU<br>ORAL; GRANULE, FOR RECONSTITUTION               |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                                   |           | 2            |             | 08/07/81         | 520 |                  |
| FLAVOR 57820/A<br>ORAL; POWDER                                     |           | 1            |             |                  |     |                  |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |                  |
| FLORASYNTH<br>ORAL; SOLUTION                                       |           | 1            |             |                  |     |                  |
| FLOUR<br>ORAL; TABLET  |           | 2            |             | 02/06/78         | 600 | 0.44MG           |
| ORAL; TABLET, COATED   |           | 5            |             | 01/04/82         | 600 | 0.28MG - 11.25MG |
| ORAL; TABLET, SUSTAINED ACTION                                     |           | 2            |             | 05/14/85         | UNK |                  |
| FLUOROCHLOROHYDROCARBONS<br>INHALATION; AEROSOL, METERED           |           | 1            |             |                  |     |                  |
| FORMALDEHYDE SOLUTION<br>TOPICAL; EMULSION, CREAM                  | 008006073 | 1            |             |                  |     |                  |
| FRAGRANCE BOUQUET 10328<br>TOPICAL; EMULSION, CREAM                |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                  |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| FRAGRANCE CHEMODERM 6411<br>TOPICAL; EMULSION, CREAM    |           | 1            |             |                  |     |                  |
| FRAGRANCE CREAM #73457<br>TOPICAL; OIL                  |           | 1            |             |                  |     |                  |
| FRAGRANCE FELTON 066M<br>TOPICAL; SOLUTION              |           | 1            |             |                  |     |                  |
| FRAGRANCE GARDENIA<br>TOPICAL; OINTMENT                 |           | 1            |             |                  |     |                  |
| FRAGRANCE GIVAUDAN ESS 9090/1C<br>TOPICAL; SOLUTION     |           | 1            |             |                  |     |                  |
| FRAGRANCE H-6540<br>TOPICAL; SPONGE                     |           | 1            |             |                  |     |                  |
| FRAGRANCE H-6540<br>TOPICAL; LOTION                     |           | 1            |             |                  |     |                  |
| FRAGRANCE P O FL-147<br>TOPICAL; EMULSION, AEROSOL FOAM |           | 1            |             |                  |     |                  |
| FRAGRANCE PA 52805<br>TOPICAL; SOLUTION                 |           | 1            |             |                  |     |                  |
| FRAGRANCE PERA DERM D<br>TOPICAL; SWAB                  |           | 1            |             |                  |     |                  |
| FRAGRANCE PERA DERM D<br>TOPICAL; SOLUTION              |           | 1            |             |                  |     |                  |
| FRAGRANCE RBD-9819<br>TOPICAL; SWAB                     |           | 1            |             |                  |     |                  |
| FRAGRANCE RBD-9819<br>TOPICAL; EMULSION, AEROSOL FOAM   |           | 1            |             |                  |     |                  |
| FRAGRANCE RBD-9819<br>TOPICAL; EMULSION, CREAM          |           | 2            |             |                  |     |                  |
| FRAGRANCE RBD-9819<br>TOPICAL; LOTION                   |           | 1            |             | 12/19/74         | UNK | 0.06%            |
| FRAGRANCE SPICY METHOLATED EUGENOL<br>TOPICAL; LOTION   |           | 1            |             |                  |     |                  |
| FRAGRANCE UNGERER N5195<br>TOPICAL; LOTION              |           | 1            |             |                  |     |                  |
| FRAGRANCE UNSPECIFIED<br>ORAL; TABLET, FILM COATED      |           | 4            |             | 09/28/77         | 600 |                  |
| FRAGRANCE UNSPECIFIED<br>TOPICAL; EMULSION, CREAM       |           | 3            |             | 09/20/85         | 600 |                  |
| FRAGRANCE UNSPECIFIED<br>TOPICAL; LOTION                |           | 2            |             | 05/02/90         | UNK |                  |
| FRAGRANCE UNSPECIFIED<br>TOPICAL; SHAMPOO               |           | 1            |             |                  |     |                  |
| FRAGRANCE UNSPECIFIED<br>TOPICAL; SOLUTION              |           | 3            |             | 01/28/92         | 600 |                  |
| FRAGRANCE UNSPECIFIED<br>TOPICAL; SPONGE                |           | 1            |             |                  |     |                  |
| FRAGRANCE UNSPECIFIED<br>TOPICAL; SUSPENSION, SHAMPOO   |           | 1            |             |                  |     |                  |
| FRAGRANCE 91-122<br>TOPICAL; SUSPENSION, SHAMPOO        |           | 1            |             |                  |     |                  |
| FRUCTOSE<br>ORAL; POWDER, FOR RECONSTITUTION            | 007660255 | 1            |             |                  |     |                  |
| FRUCTOSE<br>ORAL; SOLUTION                              |           | 3            |             | 12/03/86         | 600 |                  |
| FUMARIC ACID<br>ORAL; CAPSULE, SUSTAINED ACTION         | 000110178 | 3            |             | 08/10/92         | 110 | 15.0MG - 120.0MG |
| FUMARIC ACID<br>ORAL; SUSPENSION                        |           | 2            |             | 03/30/94         | 600 | 0.5%             |
| FUMARIC ACID<br>ORAL; TABLET                            |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| FUMARIC ACID                                   | 000110178 | 1            |             |                  |     |                     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| GALACTOSE, D-                                  | 000059234 | 6            |             | 08/25/92         | 600 | 14.667%             |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 2            |             | 08/25/92         | 600 | 14.667%             |
| RECTAL; SOLUTION                               |           | 1            |             |                  |     |                     |
| GAMMA-CYCLODEXTRIN                             |           | 1            |             |                  |     |                     |
| INTRAVENOUS; INJECTION                         | 009000708 | 3            |             | 07/06/87         | 600 | 16.6% - 16.7%       |
| GELATIN  |           | 2            |             | 11/21/84         | 600 | 9.0MG - 14.0MG      |
| DENTAL; PASTE                                  |           | 2            |             | 09/12/57         | 510 | 16.0%               |
| IM - IV - SC; POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                     |
| IM - SC; INJECTION, SUSTAINED ACTION           |           | 2            |             |                  |     |                     |
| INHALATION; CAPSULE, HARD GELATIN              |           | 2            |             | 01/21/94         | 510 |                     |
| INTRAMUSCULAR; INJECTION                       |           | 4            |             | 04/17/78         | 160 |                     |
| INTRAVENOUS; SOLUTION                          |           | 1            |             |                  |     |                     |
| IV(INFUSION); INJECTION                        |           | 472          |             | 12/20/95         | 520 | 3.84MG - 756.0MG    |
| ORAL; CAPSULE                                  |           | 2            |             | 01/29/93         | 600 |                     |
| ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GEL |           | 3            |             | 06/30/92         | 600 |                     |
| ORAL; CAPSULE, COATED PELLETS                  |           | 5            |             | 05/10/95         | 180 |                     |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 10           |             | 12/06/95         | 530 | 48.5MG              |
| ORAL; CAPSULE, HARD GELATIN                    |           | 12           |             | 11/22/95         | 150 | 54.72MG - 303.065MG |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 45           |             | 09/11/95         | 110 | 0.2MG - 50.46MG     |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                     |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                     |
| ORAL; PASTILLE                                 |           | 1            |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 6            |             | 05/28/91         | 600 |                     |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                     |
| ORAL; SOLUTION, ELIXIR                         |           | 71           |             | 02/21/95         | 600 | 0.002GM - 0.02GM    |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 28           |             | 09/10/87         | 600 | 0.19MG - 21.06MG    |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 5            |             | 04/19/95         | 110 | 0.68MG - 20.151MG   |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                     |
| ORAL; TABLET, REPEAT ACTION                    |           | 8            |             | 01/22/87         | 600 | 2.1MG - 40.0MG      |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                     |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                     |
| SUBLINGUAL; TABLET                             |           | 1            |             |                  |     |                     |
| TOPICAL; PASTE                                 |           | 1            |             |                  |     |                     |
| VAGINAL; SUPPOSITORY                           |           | 1            |             |                  |     |                     |
| GELATIN 200 BLOOM                              |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| GELLAN GUM                                     | 071010521 | 1            |             |                  |     |                     |
| OPHTHALMIC; SOLUTION                           |           | 1            |             |                  |     |                     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| GELUCIRE 33/01<br>ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |     |                   |
| GENTISIC ACID<br>INTRAVENOUS; INJECTION                          | 000490799 | 1            |             |                  |     |                   |
| GENTISIC ACID ETHANOLAMIDE<br>IV(INFUSION); INJECTION            |           | 2            |             | 08/08/85         | 510 | 1.0%              |
| GINGER FLUIDEXTRACT<br>ORAL; SOLUTION, ELIXIR                    |           | 1            |             |                  |     |                   |
| GLUCEPTATE SODIUM<br>INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | 013007857 | 1            |             |                  |     |                   |
| GLUCONOLACTONE<br>INTRAVENOUS; INJECTION                         | 000090802 | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, AEROSOL FOAM                                  |           | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION  |           | 2            |             | 12/24/84         | 520 | 0.25%             |
| TOPICAL; SPONGE  |           | 1            |             |                  |     |                   |
| GLUCOSE, LIQUID<br>ORAL; PASTILLE                                | 008027563 | 1            |             |                  |     |                   |
| ORAL; SOLUTION   |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |                   |
| ORAL; SYRUP  |           | 6            |             | 04/18/84         | UNK | 0.275% - 62.0%    |
| GLUCURONIC ACID<br>INTRAVENOUS; INJECTION                        |           | 1            |             |                  |     |                   |
| GLUTAMIC ACID HYDROCHLORIDE<br>ORAL; CAPSULE                     | 000138158 | 1            |             |                  |     |                   |
| GLUTAMIC ACID, DL-<br>VAGINAL; EMULSION, CREAM                   | 000617652 | 1            |             |                  |     |                   |
| GLUTEN<br>ORAL; TABLET   | 008002800 | 1            |             |                  |     |                   |
| GLYCERIN<br>BUCCAL; GUM, CHEWING                                 | 000056815 | 2            |             | 06/08/92         | UNK |                   |
| DENTAL; SOLUTION   |           | 4            |             | 12/28/95         | 600 | 7.188% - 98.4%    |
| IM - IV; INJECTION   |           | 1            |             |                  |     |                   |
| IM - SC; INJECTION   |           | 1            |             |                  |     |                   |
| INHALATION; SOLUTION   |           | 15           |             | 11/22/88         | 600 | 0.125% - 8.0%     |
| INTRADERMAL; INJECTION   |           | 2            |             | 02/08/77         | 510 | 1.6%              |
| INTRAMUSCULAR; INJECTION   |           | 1            |             |                  |     |                   |
| INTRAVENOUS; EMULSION, INJECTION                                 |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION   |           | 3            |             | 06/18/93         | 120 | 2.25% - 2.5%      |
| IV(INFUSION); INJECTION  |           | 9            |             | 12/30/93         | 510 | 1.7% - 2.5%       |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION, LYOPHILI           |           | 1            |             |                  |     |                   |
| NASAL; SOLUTION  |           | 2            |             | 05/18/70         | 510 | 2.5%              |
| OPHTHALMIC; SOLUTION   |           | 7            |             | 09/29/95         | 600 | 0.5% - 3.0%       |
| OPHTHALMIC; SUSPENSION   |           | 2            |             | 07/10/73         | UNK | 2.2%              |
| ORAL; CAPSULE  |           | 49           |             | 07/30/93         | 600 | 0.789MG - 204.2MG |
| ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GEL                   |           | 2            |             | 01/29/93         | 600 |                   |
| ORAL; CAPSULE, COATED, SOFT GELATIN                              |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, HARD GELATIN                                      |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| GLYCERIN                                       | 000056815 |              |             |                  |     |                   |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 12           |             | 11/22/95         | 150 | 3.055MG - 111.0MG |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 3            |             | 04/25/95         | UNK | 0.1MG             |
| ORAL; CONCENTRATE                              |           | 18           |             | 11/30/94         | 600 | 5.0% - 86.6%      |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION                                 |           | 37           |             | 11/11/95         | 600 | 2.5% - 20.0%      |
| ORAL; SOLUTION, ELIXIR                         |           | 15           |             | 04/29/93         | 600 | 2.5% - 5.0%       |
| ORAL; SUSPENSION                               |           | 33           |             | 06/16/95         | UNK | 1.0% - 34.3%      |
| ORAL; SYRUP                                    |           | 54           |             | 07/30/93         | 600 | 5.0% - 50.0%      |
| ORAL; TABLET                                   |           | 9            |             | 02/21/95         | 600 | 0.04ML            |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 07/29/92         | 600 | 0.75MG - 1.0MG    |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 11/18/83         | 600 |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 2            |             | 08/19/91         | UNK | 1.2MG             |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                   |
| OTIC; SOLUTION                                 |           | 5            |             | 12/29/95         | 600 | 52.62%            |
| OTIC; SUSPENSION                               |           | 2            |             | 05/25/75         | 600 | 0.05%             |
| PERFUSION, BILIARY; LIQUID                     |           | 1            |             |                  |     |                   |
| RECTAL; SUPPOSITORY                            |           | 5            |             | 11/24/93         | 600 |                   |
| SUBCUTANEOUS; INJECTION                        |           | 13           |             | 03/31/94         | 510 | 1.6% - 32.5%      |
| SUBCUTANEOUS; SUSPENSION, INJECTION            |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, AEROSOL FOAM                |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                       |           | 41           |             | 09/20/95         | UNK | 0.2% - 21.0%      |
| TOPICAL; LOTION                                |           | 9            |             | 05/31/89         | UNK | 3.0% - 10.0%      |
| TOPICAL; OINTMENT                              |           | 2            |             | 03/09/78         | 600 | 5.0%              |
| TOPICAL; SOLUTION                              |           | 4            |             | 01/28/92         | 600 | 3.43% - 65.7%     |
| TOPICAL; SPONGE                                |           | 1            |             |                  |     |                   |
| TRANSDERMAL; FILM, CONTROLLED RELEASE          |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM                       |           | 4            |             | 09/19/85         | 600 | 5.0% - 7.0%       |
| VAGINAL; SUPPOSITORY                           |           | 3            |             | 01/27/87         | 520 | 227.9MG           |
| GLYCERIN HYDROCHLORIDE                         |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| GLYCEROL ESTER OF HYDROGENATED ROSIN           | 008050291 |              |             |                  |     |                   |
| NASAL; OINTMENT                                |           | 1            |             |                  |     |                   |
| GLYCERYL BEHENATE                              |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 2            |             | 11/22/91         | 600 |                   |
| GLYCERYL DISTEARATE                            | 001323837 |              |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 4            |             | 01/06/81         | UNK | 6.6MG - 39.2MG    |
| GLYCERYL LAURATE                               | 001322889 |              |             |                  |     |                   |
| TRANSDERMAL; FILM, CONTROLLED RELEASE          |           | 1            |             |                  |     |                   |
| GLYCERYL OLEATE                                | 000544763 |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 2            |             | 01/27/81         | 120 |                   |
| ORAL; CAPSULE, HARD GELATIN                    |           | 2            |             | 03/28/67         | UNK |                   |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET                                |           | 2            |             | 11/17/95         | 510 | 0.15MG            |
| TRANSDERMAL; FILM, CONTROLLED RELEASE          |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                     | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| GLYCERYL OLEATE/PROPYLENE GLYCOL<br>TOPICAL; CREAM, AUGMENTED       |           | 1            |             |                  |     |                   |
| GLYCERYL PALMITATE<br>RECTAL; SUPPOSITORY                           | 001330730 | 2            |             | 04/30/73         | 120 |                   |
| GLYCERYL RICINOLEATE<br>TOPICAL; SUSPENSION, SHAMPOO                | 001323382 | 4            |             | 01/10/91         | 600 | 1.0% - 2.0%       |
| GLYCERYL STEARATE<br>OPHTHALMIC; SUSPENSION                         | 031566311 | 2            |             | 05/11/88         | 600 | 0.5%              |
| ORAL; CAPSULE, SUSTAINED ACTION                                     |           | 5            |             | 08/02/76         | 120 | 0.823MG - 27.0MG  |
| ORAL; TABLET, SUSTAINED ACTION                                      |           | 5            |             | 01/04/95         | 600 | 52.86MG - 154.0MG |
| OTIC; SUSPENSION  |           | 2            |             | 09/29/87         | 600 | 0.05% - 0.5%      |
| RECTAL; SUPPOSITORY   |           | 7            |             | 11/24/93         | 600 | 6.0MG - 36.85MG   |
| TOPICAL; EMULSION, AEROSOL FOAM                                     |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM  |           | 44           |             | 09/13/95         | UNK | 0.3% - 20.0%      |
| TOPICAL; LOTION   |           | 12           |             | 12/07/92         | UNK | 0.25% - 3.0%      |
| TOPICAL; OINTMENT   |           | 4            |             | 10/10/85         | 600 | 5.0%              |
| VAGINAL; EMULSION, CREAM  |           | 12           |             | 12/21/95         | 520 | 2.0% - 17.0%      |
| GLYCERYL STEARATE SE<br>TOPICAL; LOTION                             |           | 1            |             |                  |     |                   |
| GLYCERYL STEARATE-STEARAMIDOETHYL DIETHYLAMINE<br>TOPICAL; OINTMENT |           | 1            |             |                  |     |                   |
| GLYCERYL STEARATE/PEG-100 STEARATE<br>TOPICAL; EMULSION, CREAM      |           | 2            |             | 04/01/94         | UNK | 5.0%              |
| TOPICAL; LOTION   |           | 2            |             | 11/26/85         | 600 | 1.42%             |
| GLYCERYL STEARATE/PEG-40 STEARATE<br>RECTAL; SUPPOSITORY            |           | 4            |             | 02/27/95         | 600 | 15.0MG - 35.0MG   |
| GLYCINE<br>INTRAMUSCULAR; INJECTION                                 | 000056406 | 1            |             |                  |     |                   |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED          |           | 1            |             |                  |     |                   |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION                        |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE   |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                                    |           | 2            |             | 12/23/91         | 520 | 2.1%              |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 3            |             | 06/01/84         | 600 | 8.0MG - 163.31MG  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                      |           | 2            |             | 07/22/85         | 520 | 100.0MG - 200.0MG |
| RECTAL; SOLUTION  |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION                        |           | 2            |             | 11/11/95         | 510 |                   |
| GLYCOL STEARATE<br>TOPICAL; SUSPENSION, SHAMPOO                     | 000111604 | 1            |             |                  |     |                   |
| GLYCYRRHIZA<br>ORAL; POWDER, FOR RECONSTITUTION                     |           | 1            |             |                  |     |                   |
| GLYCYRRHIZIN, AMMONIATED<br>ORAL; GRANULE                           | 001407030 | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                                    |           | 1            |             |                  |     |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                      |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| GUANIDINE HYDROCHLORIDE<br>INTRAVENOUS; INJECTION | 000050011 | 2            |             | 02/23/76         | 160 | 0.04%            |
| GUAR GUM  | 009000300 | 1            |             |                  |     |                  |
| BUCCAL/SUBLINGUAL; TABLET                         |           | 2            |             | 04/18/91         | 600 | 0.2%             |
| ORAL; POWDER, FOR RECONSTITUTION                  |           | 1            |             |                  |     |                  |
| ORAL; SUSPENSION                                  |           | 8            |             | 12/01/86         | 600 | 1.296MG - 12.0MG |
| ORAL; TABLET                                      |           | 4            |             | 01/06/78         | 110 | 6.0MG - 35.4MG   |
| ORAL; TABLET, FILM COATED                         |           | 3            |             | 06/10/83         | UNK | 4.0MG - 5.04MG   |
| ORAL; TABLET, SUSTAINED ACTION                    |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION                                   |           | 1            |             |                  |     |                  |
| VAGINAL; TABLET                                   |           | 1            |             |                  |     |                  |
| GUM BASE, CHEWING                                 |           | 2            |             | 06/08/92         | UNK |                  |
| BUCCAL; GUM, CHEWING                              |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                      |           |              |             |                  |     |                  |
| GUM ROSIN   | 008050100 | 1            |             |                  |     |                  |
| ORAL; TABLET, REPEAT ACTION                       |           | 4            |             | 11/14/94         | UNK | 9.0MG            |
| ORAL; TABLET, SUSTAINED ACTION                    |           | 1            |             |                  |     |                  |
| GUM, NATURAL                                      |           |              |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                    |           |              |             |                  |     |                  |
| HERBACOL  | 006365839 | 1            |             |                  |     |                  |
| TOPICAL; SOLUTION                                 |           | 1            |             |                  |     |                  |
| TOPICAL; SPONGE                                   |           |              |             |                  |     |                  |
| HEXYLENE GLYCOL                                   | 000107415 | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM                          |           | 2            |             | 04/30/87         | UNK | 12.0%            |
| TOPICAL; OINTMENT                                 |           |              |             |                  |     |                  |
| HIGH FRUCTOSE CORN SYRUP                          |           | 1            |             |                  |     |                  |
| ORAL; SUSPENSION, SUSTAINED ACTION                |           |              |             |                  |     |                  |
| HISTIDINE   | 000071001 | 1            |             |                  |     |                  |
| INTRAVENOUS; SUSPENSION, INJECTION                |           |              |             |                  |     |                  |
| HYDROCARBON GEL, PLASTICIZED                      | 008049658 | 1            |             |                  |     |                  |
| DENTAL; PASTE                                     |           | 1            |             |                  |     |                  |
| OPHTHALMIC; OINTMENT                              |           | 4            |             | 10/29/82         | UNK |                  |
| TOPICAL; OINTMENT                                 |           |              |             |                  |     |                  |
| HYDROCHLORIC ACID                                 | 007647010 | 15           |             | 10/13/87         | 600 | 1.414% - 2.827%  |
| CAUDAL BLOCK; INJECTION                           |           | 1            |             |                  |     |                  |
| DENTAL; SOLUTION                                  |           | 31           |             | 10/30/92         | UNK |                  |
| EPIDURAL; INJECTION                               |           | 50           |             | 12/29/93         | 600 |                  |
| IM - IV - SC; INJECTION                           |           | 113          |             | 12/27/94         | 600 | 0.00022%         |
| IM - IV; INJECTION                                |           | 11           |             | 10/30/95         | 600 |                  |
| IM - IV; POWDER, FOR INJECTION SOLUTION           |           | 3            |             | 03/05/90         | 600 |                  |
| IM - IV; SOLUTION, INJECTION                      |           | 10           |             | 01/23/85         | 510 |                  |
| IM - SC; INJECTION                                |           | 1            |             |                  |     |                  |
| IM - SC; POWDER, FOR INJECTION SOLUTION           |           | 3            |             | 09/03/92         | 510 | 0.7% - 1.72%     |
| INHALATION; AEROSOL, METERED                      |           | 23           |             | 07/28/95         | 600 |                  |
| INHALATION; SOLUTION                              |           | 1            |             |                  |     |                  |
| INTERSTITIAL; INJECTION                           |           |              |             |                  |     |                  |
| INTRA-ARTICULAR; INJECTION                        |           | 12           |             | 11/05/81         | 600 |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| HYDROCHLORIC ACID  | 007647010 |              |             |                  |     |                 |
| INTRABURSAL; INJECTION                                     |           | 2            |             | 09/30/64         | UNK |                 |
| INTRACARDIAC; INJECTION                                    |           | 3            |             | 06/01/88         | 600 |                 |
| INTRACAVITARY; INJECTION                                   |           | 1            |             |                  |     |                 |
| INTRACAVITARY; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED |           | 1            |             |                  |     |                 |
| INTRADERMAL; INJECTION                                     |           | 5            |             | 10/16/87         | UNK |                 |
| INTRALESIONAL; INJECTION                                   |           | 8            |             | 10/16/87         | UNK |                 |
| INTRAMUSCULAR; INJECTION                                   |           | 51           |             | 10/29/92         | 510 |                 |
| INTRAMUSCULAR; SOLUTION, INJECTION                         |           | 2            |             | 04/17/95         | UNK |                 |
| INTRAOCULAR; SOLUTION                                      |           | 2            |             | 04/28/95         | 600 |                 |
| INTRAPERITONEAL; INJECTION                                 |           | 1            |             |                  |     |                 |
| INTRAPERITONEAL; SOLUTION                                  |           | 5            |             | 08/19/97         | 160 |                 |
| INTRAPLEURAL; INJECTION                                    |           | 1            |             |                  |     |                 |
| INTRASYNOVIAL; INJECTION                                   |           | 5            |             | 11/05/81         | 600 |                 |
| INTRATHECAL; INJECTION                                     |           | 13           |             | 10/30/92         | UNK |                 |
| INTRATHECAL; POWDER, FOR INJECTION SOLUTION                |           | 2            |             | 12/21/87         | 150 |                 |
| INTRATHECAL; SOLUTION                                      |           | 1            |             |                  |     |                 |
| INTRATRACHEAL; POWDER, FOR RECONSTITUTION                  |           | 1            |             |                  |     |                 |
| INTRATRACHEAL; SUSPENSION                                  |           | 1            |             |                  |     |                 |
| INTRATUMOR; INJECTION                                      |           | 1            |             |                  |     |                 |
| INTRATUMOR; POWDER, FOR INJECTION SOLUTION                 |           | 1            |             |                  |     |                 |
| INTRAVASCULAR; INJECTION                                   |           | 4            |             | 01/27/97         | 160 |                 |
| INTRAVASCULAR; SOLUTION                                    |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                                     |           | 165          |             | 08/18/95         | 110 | 1.414% - 10.0%  |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                |           | 14           |             | 04/19/95         | 600 |                 |
| INTRAVENOUS; SOLUTION                                      |           | 7            |             | 12/26/85         | 160 | 0.9%            |
| INTRAVENOUS; SUSPENSION, INJECTION                         |           | 1            |             |                  |     |                 |
| IONTOPHORESIS; SOLUTION                                    |           | 1            |             |                  |     |                 |
| IRRIGATION; SOLUTION                                       |           | 7            |             | 11/27/91         | 600 |                 |
| IV - SC; INJECTION   |           | 23           |             | 10/10/95         | 600 |                 |
| IV - SC; POWDER, FOR INJECTION SOLUTION                    |           | 2            |             | 08/31/90         | 600 |                 |
| IV(INFUSION); INJECTION                                    |           | 176          |             | 08/18/95         | 110 | 1.414% - 2.827% |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION               |           | 7            |             | 12/21/90         | 600 |                 |
| IV(INFUSION); SOLUTION                                     |           | 1            |             |                  |     |                 |
| NASAL; SOLUTION  |           | 3            |             | 12/26/90         | 510 |                 |
| NASAL; SPRAY   |           | 1            |             |                  |     |                 |
| NASAL; SPRAY, METERED                                      |           | 11           |             | 10/20/95         | UNK |                 |
| NERVE BLOCK; INJECTION                                     |           | 58           |             | 06/23/95         | 600 | 1.36% - 2.827%  |
| OPHTHALMIC; GEL  |           | 1            |             |                  |     |                 |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                     |           | 1            |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                                       |           | 61           |             | 12/29/95         | 600 |                 |
| OPHTHALMIC; SUSPENSION                                     |           | 14           |             | 09/13/95         | 600 |                 |
| ORAL; CONCENTRATE  |           | 6            |             | 06/30/92         | 600 | 0.217% - 0.47%  |
| ORAL; SOLUTION   |           | 24           |             | 10/24/95         | 160 | 0.9%            |
| ORAL; SUSPENSION   |           | 6            |             | 03/18/87         | 600 | 10.0%           |
| ORAL; SYRUP  |           | 6            |             | 10/28/94         | 600 |                 |
| OTIC; SOLUTION   |           | 6            |             | 12/29/95         | 600 | 0.56%           |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| HYDROCHLORIC ACID                              | 007647010 |              |             |                  |     |                 |
| OTIC; SUSPENSION                               |           | 1            |             |                  |     |                 |
| PERFUSION/CARDIAC; SOLUTION                    |           | 1            |             |                  |     |                 |
| PERIDURAL; INJECTION                           |           | 1            |             |                  |     |                 |
| RECTAL; SOLUTION                               |           | 2            |             | 10/24/95         | 160 |                 |
| RETROBULBAR; INJECTION                         |           | 1            |             |                  |     |                 |
| SOFT TISSUE; INJECTION                         |           | 6            |             | 06/19/80         | 600 |                 |
| SPINAL; INJECTION                              |           | 5            |             | 12/11/87         | 600 |                 |
| SUBCONJUNCTIVAL; INJECTION                     |           | 1            |             |                  |     |                 |
| SUBCUTANEOUS; INJECTION                        |           | 19           |             | 03/31/94         | 510 |                 |
| SUBCUTANEOUS; SOLUTION, INJECTION              |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION                              |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, AEROSOL FOAM                |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                       |           | 2            |             | 10/08/85         | 600 |                 |
| TOPICAL; GEL                                   |           | 2            |             | 02/07/89         | 600 |                 |
| TOPICAL; GEL, JELLY                            |           | 3            |             | 04/29/93         | 600 |                 |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                 |
| TOPICAL; SHAMPOO                               |           | 2            |             | 08/31/90         | UNK |                 |
| TOPICAL; SOLUTION                              |           | 9            |             | 07/31/84         | 600 |                 |
| URETERAL; SOLUTION                             |           | 1            |             |                  |     |                 |
| HYDROCHLORIC ACID, DILUTED                     |           |              |             |                  |     |                 |
| INTRA-ARTERIAL; INJECTION                      |           | 1            |             |                  |     |                 |
| INTRAVASCULAR; INJECTION                       |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                         |           | 1            |             |                  |     |                 |
| IV(INFUSION); SOLUTION, INJECTION              |           | 1            |             |                  |     |                 |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                 |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                 |
| HYDROGEN PEROXIDE                              | 007722841 |              |             |                  |     |                 |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                 |
| TOPICAL; SPONGE                                |           | 2            |             | 01/07/87         | 520 |                 |
| HYDROXYETHYL CELLULOSE                         | 009004620 |              |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                           |           | 3            |             | 06/29/76         | 600 | 0.25% - 0.35%   |
| OPHTHALMIC; SUSPENSION                         |           | 4            |             | 07/21/89         | UNK | 0.05% - 0.35%   |
| ORAL; SYRUP                                    |           | 4            |             | 07/22/92         | 600 |                 |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 3            |             | 11/08/93         | UNK | 10.0MG - 20.0MG |
| OTIC; SOLUTION                                 |           | 1            |             |                  |     |                 |
| TOPICAL; SOLUTION                              |           | 2            |             | 01/22/88         | 520 | 0.5% - 0.75%    |
| TOPICAL; SPONGE                                |           | 1            |             |                  |     |                 |
| TRANSDERMAL; FILM, CONTROLLED RELEASE          |           | 1            |             |                  |     |                 |
| HYDROXYMETHYL CELLULOSE                        |           |              |             |                  |     |                 |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                 |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                 |
| HYDROXYPROPYL CELLULOSE                        | 009004642 |              |             |                  |     |                 |
| ORAL; CAPSULE                                  |           | 4            |             | 01/25/95         | 600 | 10.0MG - 36.0MG |
| ORAL; CAPSULE, COATED PELLETS                  |           | 2            |             | 10/30/85         | 600 |                 |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 2            |             | 10/05/95         | 180 |                 |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV  | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|------|-------------------|
| HYDROXYPROPYL CELLULOSE                      | 009004642 |              |             |                  |      |                   |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 9            |             | 01/04/95         | 600  | 0.2MG - 5.49MG    |
| ORAL; GRANULE, FOR RECONSTITUTION            |           | 1            |             |                  |      |                   |
| ORAL; POWDER, FOR RECONSTITUTION             |           | 1            |             |                  |      |                   |
| ORAL; TABLET                                 |           | 168          |             | 11/09/95         | 600  | 0.05MG - 46.0MG   |
| ORAL; TABLET, COATED                         |           | 14           |             | 06/20/88         | 600  | 0.5MG - 1.0MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 2            |             | 06/19/95         | 520  | 15.0MG            |
| ORAL; TABLET, ENTERIC COATED PARTICLES       |           | 1            |             |                  |      |                   |
| ORAL; TABLET, FILM COATED                    |           | 47           |             | 12/11/95         | 530  | 0.58MG            |
| ORAL; TABLET, SUSTAINED ACTION               |           | 15           |             | 03/30/95         | 110  | 2.0MG - 37.5MG    |
| SUBLINGUAL; TABLET                           |           | 1            |             |                  |      |                   |
| TOPICAL; GEL                                 |           | 5            |             | 01/29/93         | 600  | 2.1% - 3.0%       |
| TOPICAL; LOTION                              |           | 2            |             | 02/20/89         | 111K | 0.15% - 0.54%     |
| TOPICAL; LOTION, AUGMENTED                   |           | 1            |             |                  |      |                   |
| TOPICAL; SOLUTION                            |           | 2            |             | 07/03/85         | 600  | 0.05%             |
| TRANSDERMAL; FILM, CONTROLLED RELEASE        |           | 1            |             |                  |      |                   |
| HYDROXYPROPYL METHYLCELLULOSE                | 009004653 |              |             |                  |      |                   |
| OPHTHALMIC; SOLUTION                         |           | 6            |             | 10/31/95         | 600  | 0.1% - 0.5%       |
| OPHTHALMIC; SUSPENSION                       |           | 13           |             | 09/13/95         | 600  | 0.002% - 0.6%     |
| ORAL; CAPSULE                                |           | 15           |             | 09/11/92         | 530  | 1.58MG - 150.0MG  |
| ORAL; CAPSULE, COATED PELLETS                |           | 2            |             | 10/30/85         | 600  |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS        |           | 2            |             | 10/05/95         | 180  |                   |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 6            |             | 05/29/92         | 110  | 1.4MG - 119.7MG   |
| ORAL; CONCENTRATE                            |           | 1            |             |                  |      |                   |
| ORAL; GRANULE, ENTERIC COATED                |           | 1            |             |                  |      |                   |
| ORAL; SUSPENSION                             |           | 1            |             |                  |      |                   |
| ORAL; SYRUP                                  |           | 3            |             | 04/29/93         | 600  | 0.45%             |
| ORAL; TABLET                                 |           | 317          |             | 10/04/95         | 510  | 0.4MG - 48.0MG    |
| ORAL; TABLET, COATED                         |           | 15           |             | 05/24/88         | 600  | 1.54MG - 6.04MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 3            |             | 11/30/95         | 600  | 3.0MG - 18.7MG    |
| ORAL; TABLET, FILM COATED                    |           | 97           |             | 12/27/95         | 150  | 0.764MG - 170.0MG |
| ORAL; TABLET, SUSTAINED ACTION               |           | 35           |             | 03/30/95         | 110  | 2.81MG - 240.0MG  |
| ORAL-21; TABLET                              |           | 1            |             |                  |      |                   |
| ORAL-28; TABLET                              |           | 1            |             |                  |      |                   |
| TOPICAL; GEL, JELLY                          |           | 2            |             | 04/29/93         | 600  | 3.5%              |
| TOPICAL; SOLUTION                            |           | 1            |             |                  |      |                   |
| VAGINAL; TABLET                              |           | 1            |             |                  |      |                   |
| HYDROXYPROPYL METHYLCELLULOSE PHTHALATE      |           |              |             |                  |      |                   |
| ORAL; CAPSULE, COATED PELLETS                |           | 3            |             | 06/30/92         | 600  |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS        |           | 2            |             | 10/05/95         | 180  |                   |
| ORAL; GRANULE, FOR RECONSTITUTION            |           | 1            |             |                  |      |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 2            |             | 03/29/82         | 600  | 29.2MG - 44.57MG  |
| ORAL; TABLET, ENTERIC COATED PARTICLES       |           | 1            |             |                  |      |                   |
| HYDROXYPROPYL METHYLCELLULOSE 2208           | 009004653 |              |             |                  |      |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 6            |             | 04/28/95         | 600  | 30.0MG - 250.0MG  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| HYDROXYPROPYL METHYLCELLULOSE 2906<br>OPHTHALMIC; SOLUTION | 009004653 | 2            |             | 07/29/94         | 600 | 0.5%             |
| ORAL; GRANULE, ENTERIC COATED                              |           | 1            |             |                  |     |                  |
| ORAL; SYRUP  |           | 1            |             |                  |     |                  |
| HYDROXYPROPYL METHYLCELLULOSE 2910<br>OPHTHALMIC; SOLUTION | 009004653 | 3            |             | 09/23/93         | UNK | 0.5%             |
| OPHTHALMIC; SUSPENSION                                     |           | 3            |             | 05/09/89         | UNK | 0.5%             |
| ORAL; CAPLET   |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE  |           | 9            |             | 04/08/94         | 530 | 1.0MG - 10.8MG   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                      |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                            |           | 2            |             | 09/11/95         | 110 | 1.17MG - 10.88MG |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |                  |
| ORAL; SYRUP  |           | 3            |             | 09/25/95         | 600 |                  |
| ORAL; TABLET   |           | 68           |             | 10/06/95         | UNK | 0.2MG - 33.0MG   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,             |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                                       |           | 9            |             | 12/30/92         | 110 | 0.7MG - 9.8MG    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED               |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                                  |           | 12           |             | 10/24/94         | 600 | 3.8MG - 60.0MG   |
| ORAL; TABLET, SUSTAINED ACTION                             |           | 11           |             | 11/18/94         | UNK | 5.7MG - 144.0MG  |
| ORAL-28; TABLET  |           | 1            |             |                  |     |                  |
| IMIDAZOLIDINYL UREA<br>TOPICAL; EMULSION, CREAM            |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                  |
| IMIDUREA<br>TOPICAL; EMULSION, CREAM                       | 039236469 | 2            |             | 06/17/94         | UNK | 0.2% - 0.3%      |
| TOPICAL; SHAMPOO   |           | 1            |             |                  |     |                  |
| INK BLACK<br>ORAL; CAPSULE                                 |           | 12           |             | 12/22/92         | 600 | 65.0MG - 102.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED               |           | 4            |             | 11/30/95         | 600 |                  |
| INK BLACK A-10450<br>ORAL; TABLET                          |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                                  |           | 1            |             |                  |     |                  |
| INK BLACK A-10509<br>ORAL; CAPSULE                         |           | 3            |             | 06/11/87         | 600 |                  |
| INK BLACK A-1057<br>ORAL; TABLET, SUSTAINED ACTION         |           | 1            |             |                  |     |                  |
| INK BLACK IMPRINTING FGE-1386<br>ORAL; CAPSULE             |           | 1            |             |                  |     |                  |
| INK BLUE BLACK A-9371<br>ORAL; CAPSULE                     |           | 1            |             |                  |     |                  |
| INK EDIBLE<br>ORAL; CAPSULE                                |           | 11           |             | 03/02/92         | 600 |                  |
| ORAL; CAPSULE, SOFT GELATIN                                |           | 2            |             | 12/30/86         | 150 |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                            |           | 5            |             | 02/28/92         | UNK |                  |
| ORAL; TABLET   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                             |           | 4            |             | 05/14/85         | UNK |                  |
| ORAL-28; TABLET  |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| INK EDIBLE BLACK                               |           | 7            |             | 03/25/94         | UNK |                     |
| ORAL; CAPSULE                                  |           | 4            |             | 02/16/88         | 600 |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| ORAL; TABLET, COATED                           |           | 2            |             | 01/09/87         | 600 | 1.0MG               |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                     |
| INK EDIBLE GRAY                                |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| INK EDIBLE RED                                 |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 2            |             | 07/13/87         | UNK |                     |
| INK EDIBLE RED A-8032                          |           | 3            |             | 03/25/94         | UNK |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| INK EDIBLE WHITE                               |           | 3            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 2            |             | 02/22/85         | 600 | 0.0007ML - 0.0011ML |
| ORAL; TABLET, FILM COATED                      |           | 3            |             | 09/25/84         | 600 |                     |
| INK FINE BLACK 2202C                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| INK FINE BLACK 2212                            |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| INK GREEN A-10454                              |           | 1            |             |                  |     |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| INK LIGHT REDWOOD                              |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| INK PINK IMPRINTING SB-1003                    |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| INK RED A-8032                                 |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| INK RED S-1-9005                               |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| INK WHITE                                      |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| INK WHITE A-8154                               |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                     |
| INK WHITE 21-K                                 |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GEL |           | 1            |             |                  |     |                     |
| INVERT SUGAR                                   | 008013170 | 1            |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 4            |             | 06/07/85         | 600 |                     |
| ORAL; SYRUP                                    |           | 2            |             | 08/29/74         | 160 | 28.2% - 37.0%       |
| IODINE   | 007553562 | 1            |             |                  |     |                     |
| INTRA-ARTERIAL; INJECTION                      |           | 1            |             |                  |     |                     |
| INTRA-ARTICULAR; INJECTION                     |           | 1            |             |                  |     |                     |
| INTRACARDIAC; INJECTION                        |           | 1            |             |                  |     |                     |
| INTRADISCAL; INJECTION                         |           | 1            |             |                  |     |                     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| IODINE                                       | 007553562 |              |             |                  |     |                    |
| INTRAVASCULAR; INJECTION                     |           | 3            |             | 08/29/78         | 160 | 20.2% - 40.0%      |
| INTRAVENOUS; INJECTION                       |           | 3            |             | 08/29/74         | 160 | 14.1% - 37.0%      |
| PERIARTICULAR; INJECTION                     |           | 1            |             |                  |     |                    |
| IOFETAMINE HYDROCHLORIDE                     |           |              |             |                  |     |                    |
| INTRAVENOUS; INJECTION                       |           | 1            |             |                  |     |                    |
| IRISH MOSS EXTRACT                           |           |              |             |                  |     |                    |
| TOPICAL; LOTION                              |           | 2            |             | 08/16/84         | 600 | 0.3%               |
| IRON OXIDE                                   |           |              |             |                  |     |                    |
| ORAL; CAPSULE                                |           | 18           |             | 03/03/95         | 110 |                    |
| ORAL; CAPSULE, ENTERIC COATED PELLETS        |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, HARD GELATIN                  |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 5            |             | 05/24/82         | 600 |                    |
| ORAL; DROPS                                  |           | 1            |             |                  |     |                    |
| ORAL; TABLET                                 |           | 30           |             | 07/12/95         | 110 | 0.04MG - 0.8MG     |
| ORAL; TABLET, COATED                         |           | 9            |             | 05/19/92         | 110 |                    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 4            |             | 10/14/94         | UNK |                    |
| ORAL; TABLET, ENTERIC COATED PARTICLES       |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                    |           | 11           |             | 06/01/95         | 120 | 0.25MG             |
| ORAL; TABLET, SUSTAINED ACTION               |           | 6            |             | 12/24/92         | 120 | 0.3MG - 0.576MG    |
| ORAL-21; TABLET                              |           | 1            |             |                  |     |                    |
| ORAL-28; TABLET                              |           | 1            |             |                  |     |                    |
| IRON OXIDE, BROWN                            |           |              |             |                  |     |                    |
| ORAL; CAPSULE                                |           | 2            |             | 04/30/92         | 600 |                    |
| ORAL; TABLET                                 |           | 3            |             | 09/24/86         | 600 |                    |
| ORAL; TABLET, FILM COATED                    |           | 1            |             |                  |     |                    |
| IRON OXIDE, RED-BROWN                        |           |              |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION               |           | 1            |             |                  |     |                    |
| IRON OXIDE, YELLOW                           |           |              |             |                  |     |                    |
| ORAL; CAPSULE                                |           | 19           |             | 10/18/95         | 600 | 0.0608MG - 0.8MG   |
| ORAL; CAPSULE, HARD GELATIN                  |           | 3            |             | 05/03/95         | 530 |                    |
| ORAL; CAPSULE, SOFT GELATIN                  |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 2            |             | 11/30/93         | 600 |                    |
| ORAL; TABLET                                 |           | 26           |             | 11/30/95         | 510 | 0.02MG - 2.0MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                    |           | 11           |             | 12/19/95         | 180 | 0.0015MG - 0.092MG |
| ORAL; TABLET, SUSTAINED ACTION               |           | 2            |             | 03/30/95         | 110 | 0.04MG             |
| ORAL-21; TABLET                              |           | 1            |             |                  |     |                    |
| ISOBUTANE                                    | 000075285 |              |             |                  |     |                    |
| TOPICAL; AEROSOL SPRAY                       |           | 3            |             | 05/24/77         | UNK | 77.6%              |
| ISOCETETH-20                                 |           |              |             |                  |     |                    |
| TOPICAL; SOLUTION                            |           | 1            |             |                  |     |                    |
| ISOCTYLACRYLATE                              |           |              |             |                  |     |                    |
| TOPICAL; TAPE                                |           | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---------------------------------------|-----------|--------------|-------------|------------------|-----|------------------|
| ISOPROPYL ALCOHOL                     | 000067630 | 3            |             | 09/10/87         | 520 |                  |
| ORAL; TABLET                          |           | 1            |             |                  |     |                  |
| TOPICAL; AEROSOL SPRAY                |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, AEROSOL FOAM       |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION                       |           | 21           |             | 09/30/94         | 600 | 2.7% - 78.0%     |
| TOPICAL; LOTION, AUGMENTED            |           | 1            |             |                  |     |                  |
| TOPICAL; OIL                          |           | 1            |             |                  |     |                  |
| TOPICAL; OINTMENT                     |           | 1            |             |                  |     |                  |
| TOPICAL; SOLUTION                     |           | 19           |             | 12/15/95         | 600 | 4.0% - 51.5%     |
| TOPICAL; SPONGE                       |           | 5            |             | 02/28/91         | 600 | 4.2MG            |
| ISOPROPYL ISOSTEARATE                 |           |              |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM              |           | 1            |             |                  |     |                  |
| ISOPROPYL MYRISTATE                   | 000110270 |              |             |                  |     |                  |
| OTIC; SUSPENSION                      |           | 1            |             |                  |     |                  |
| TOPICAL; AEROSOL                      |           | 1            |             |                  |     |                  |
| TOPICAL; AEROSOL SPRAY                |           | 2            |             | 06/15/73         | 600 | 21.96%           |
| TOPICAL; EMULSION, CREAM              |           | 33           |             | 06/17/94         | UNK | 1.0% - 10.0%     |
| TOPICAL; GEL                          |           | 3            |             | 06/06/84         | 600 | 10.0%            |
| TOPICAL; LOTION                       |           | 3            |             | 12/07/92         | UNK | 2.0%             |
| TOPICAL; OIL                          |           | 1            |             |                  |     |                  |
| TOPICAL; OINTMENT                     |           | 1            |             |                  |     |                  |
| TRANSDERMAL; FILM, CONTROLLED RELEASE |           | 1            |             |                  |     |                  |
| VAGINAL; EMULSION, CREAM              |           | 2            |             | 02/21/91         | 520 |                  |
| ISOPROPYL PALMITATE                   | 000142916 |              |             |                  |     |                  |
| TOPICAL; AEROSOL SPRAY                |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM              |           | 48           |             | 09/20/95         | UNK | 0.325% - 9.9375% |
| TOPICAL; LOTION                       |           | 5            |             | 06/13/88         | UNK | 0.6% - 5.0%      |
| TOPICAL; OINTMENT                     |           | 2            |             | 07/24/78         | 600 |                  |
| ISOPROPYL STEARATE                    |           |              |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM              |           | 1            |             |                  |     |                  |
| ISOSTEARIC ACID                       |           |              |             |                  |     |                  |
| TOPICAL; OINTMENT                     |           | 1            |             |                  |     |                  |
| ISOSTEARYL ALCOHOL                    |           |              |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM              |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION                       |           | 1            |             |                  |     |                  |
| TOPICAL; OINTMENT                     |           | 1            |             |                  |     |                  |
| ISOTONIC SODIUM CHLORIDE SOLUTION     | 008028771 |              |             |                  |     |                  |
| INTRAVENOUS; SOLUTION                 |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION                        |           | 1            |             |                  |     |                  |
| JELENE                                | 008049669 |              |             |                  |     |                  |
| TOPICAL; OINTMENT                     |           | 1            |             |                  |     |                  |
| KAOLIN                                | 001332587 |              |             |                  |     |                  |
| ORAL; CAPSULE                         |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION      |           | 1            |             |                  |     |                  |
| ORAL; SYRUP                           |           | 1            |             |                  |     |                  |
| ORAL; TABLET                          |           | 5            |             | 05/31/94         | 530 | 7.95MG - 30.4MG  |
| ORAL; TABLET, COATED                  |           | 2            |             | 09/29/76         | 600 | 2.87MG - 8.0MG   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---|-----------|--------------|-------------|------------------|-----|-----------------|
| KAOLIN  | 001332587 |              |             |                  |     |                 |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED            |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 1            |             |                  |     |                 |
| KATHON CG   |           |              |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                                |           | 1            |             |                  |     |                 |
| LAC RESIN   |           |              |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 1            |             |                  |     |                 |
| LACTATE   | 000050215 |              |             |                  |     |                 |
| TOPICAL; LOTION   |           | 1            |             |                  |     |                 |
| LACTIC ACID   | 008012213 |              |             |                  |     |                 |
| IM - IV - SC; INJECTION                                 |           | 4            |             | 01/06/76         | 600 | 0.012%          |
| IM - IV; INJECTION                                      |           | 16           |             | 08/31/95         | 600 | 0.25% - 1.1578% |
| INTRACARDIAC; INJECTION                                 |           | 3            |             | 01/06/76         | 600 | 0.012%          |
| INTRAMUSCULAR; INJECTION                                |           | 9            |             | 02/25/93         | 600 |                 |
| INTRAVENOUS; INJECTION                                  |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                                 |           | 8            |             | 08/09/94         | 110 | 0.012% - 1.86%  |
| IV(INFUSION); SOLUTION, INJECTION                       |           | 1            |             |                  |     |                 |
| ORAL; CONCENTRATE                                       |           | 8            |             | 09/28/93         | 600 | 0.00022% - 0.3% |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                 |
| ORAL; SYRUP   |           | 1            |             |                  |     |                 |
| ORAL; TABLET  |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                                |           | 25           |             | 09/20/95         | UNK | 0.015% - 2.0%   |
| TOPICAL; LOTION   |           | 4            |             | 12/30/88         | UNK | 0.51% - 6.6%    |
| TOPICAL; OINTMENT                                       |           | 3            |             | 10/01/86         | 600 |                 |
| TOPICAL; SOLUTION                                       |           | 1            |             |                  |     |                 |
| VAGINAL; EMULSION, CREAM                                |           | 2            |             | 01/27/87         | 520 | 0.81%           |
| VAGINAL; SUPPOSITORY                                    |           | 1            |             |                  |     |                 |
| VAGINAL; TABLET   |           | 1            |             |                  |     |                 |
| LACTIC ACID, DL-  | 000598823 |              |             |                  |     |                 |
| IM - IV; INJECTION                                      |           | 1            |             |                  |     |                 |
| IMPLANTATION; PELLET, IMPLANT                           |           | 2            |             | 12/18/95         | 150 |                 |
| SUBCUTANEOUS; PELLET, IMPLANT                           |           | 2            |             | 12/18/95         | 150 |                 |
| VAGINAL; SUPPOSITORY                                    |           | 1            |             |                  |     |                 |
| LACTOBIONIC ACID  | 000096822 |              |             |                  |     |                 |
| IM - IV; POWDER, FOR INJECTION SOLUTION                 |           | 1            |             |                  |     |                 |
| LACTOSE   | 000063423 |              |             |                  |     |                 |
| BUCCAL; TABLET  |           | 1            |             |                  |     |                 |
| BUCCAL/SUBLINGUAL; TABLET                               |           | 1            |             |                  |     |                 |
| IM - IV - SC; INJECTION                                 |           | 1            |             |                  |     |                 |
| IM - IV - SC; POWDER, FOR INJECTION SOLUTION            |           | 1            |             |                  |     |                 |
| IM - IV; INJECTION                                      |           | 1            |             |                  |     |                 |
| IM - IV; POWDER, FOR INJECTION SOLUTION                 |           | 2            |             | 11/20/64         | UNK |                 |
| INHALATION; CAPSULE                                     |           | 1            |             |                  |     |                 |
| INHALATION; CAPSULE, HARD GELATIN                       |           | 1            |             |                  |     |                 |
| INTRACAVITARY; POWDER, FOR INJECTION SOLUTION, LYOPHILI |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; INJECTION                                |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION           |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| LACTOSE   | 000063423 | 5            |             | 04/13/89         | 600 |                    |
| INTRAVENOUS; INJECTION                                |           | 1            |             |                  |     |                    |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION           |           | 2            |             | 05/31/89         | 600 | 0.1% - 2.5%        |
| IV(INFUSION); INJECTION                               |           | 1            |             |                  |     |                    |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION          |           | 1            |             |                  |     |                    |
| IV(INFUSION); SOLUTION, INJECTION                     |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE   |           | 288          |             | 12/29/95         | 600 | 14.805%            |
| ORAL; CAPSULE, COATED PELLETS                         |           | 2            |             | 10/30/85         | 600 |                    |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                 |           | 2            |             | 10/05/95         | 180 |                    |
| ORAL; CAPSULE, HARD GELATIN                           |           | 4            |             | 12/06/95         | 530 | 14.25MG - 100.0MG  |
| ORAL; CAPSULE, SUSTAINED ACTION                       |           | 6            |             | 02/21/92         | 110 | 21.6MG - 120.0MG   |
| ORAL; CONCENTRATE                                     |           | 1            |             |                  |     |                    |
| ORAL; GRANULE   |           | 2            |             | 05/20/88         | 600 |                    |
| ORAL; GRANULE, FOR RECONSTITUTION                     |           | 1            |             |                  |     |                    |
| ORAL; POWDER, FOR RECONSTITUTION                      |           | 1            |             |                  |     |                    |
| ORAL; SOLUTION  |           | 6            |             | 08/25/92         | 600 | 8.0%               |
| ORAL; TABLET  |           | 1,160        |             | 12/29/95         | 600 | 0.031GM - 1.02GM   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,        |           | 5            |             | 09/11/95         | 600 | 30.0MG - 117.7MG   |
| ORAL; TABLET, COATED                                  |           | 63           |             | 12/30/92         | 110 | 2.8MG - 346.5MG    |
| ORAL; TABLET, CONTROLLED RELEASE                      |           | 1            |             |                  |     |                    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED          |           | 5            |             | 11/30/95         | 600 | 40.0MG - 209.0MG   |
| ORAL; TABLET, FILM COATED                             |           | 68           |             | 12/27/95         | 150 | 1.96MG - 590.0MG   |
| ORAL; TABLET, REPEAT ACTION                           |           | 2            |             | 03/31/81         | UNK | 122.99MG - 153.2MG |
| ORAL; TABLET, SUSTAINED ACTION                        |           | 24           |             | 11/23/94         | UNK | 10.0MG - 400.0MG   |
| ORAL-21; TABLET                                       |           | 31           |             | 12/13/93         | 600 | 7.8MG - 89.007MG   |
| ORAL-28; TABLET                                       |           | 35           |             | 11/17/95         | 510 | 21.0MG - 179.2MG   |
| RECTAL; SOLUTION                                      |           | 2            |             | 08/25/92         | 600 | 8.0%               |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION          |           | 2            |             | 09/30/82         | 510 |                    |
| SUBLINGUAL; TABLET                                    |           | 12           |             | 07/29/88         | 110 | 9.967MG - 327.5MG  |
| TRANSDERMAL; OINTMENT                                 |           | 1            |             |                  |     |                    |
| VAGINAL; EMULSION, CREAM                              |           | 1            |             |                  |     |                    |
| VAGINAL; SUPPOSITORY                                  |           | 2            |             | 01/27/87         | 520 |                    |
| VAGINAL; TABLET                                       |           | 8            |             | 12/26/91         | 520 | 395.0MG - 696.0MG  |
| LACTOSE MONOHYDRATE                                   | 010039266 | 1            |             |                  |     |                    |
| IM - IV; INJECTION                                    |           | 1            |             |                  |     |                    |
| INTRAVENOUS; INJECTION                                |           | 1            |             |                  |     |                    |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION, LYOPHILI |           | 7            |             | 09/29/95         | 600 | 18.0MG - 360.0MG   |
| ORAL; CAPSULE   |           | 35           |             | 11/22/95         | 600 | 12.5MG - 370.0MG   |
| ORAL; TABLET  |           | 1            |             |                  |     |                    |
| ORAL; TABLET, ENTERIC COATED PARTICLES                |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                             |           | 2            |             | 05/24/95         | 600 | 92.04MG - 260.0MG  |
| LACTOSE MONOHYDRATE, ALPHA                            | 005989811 | 1            |             |                  |     |                    |
| ORAL; CAPSULE   |           | 1            |             |                  |     |                    |
| LACTOSE, ANHYDROUS                                    | 000063423 | 15           |             | 11/30/95         | 600 | 7.5MG - 415.8MG    |
| ORAL; CAPSULE   |           | 1            |             |                  |     |                    |
| ORAL; TABLET  |           | 1            |             |                  |     |                    |
| ORAL; TABLET, COATED                                  |           | 1            |             |                  |     |                    |

## INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| LACTOSE, ANHYDROUS   | 000063423 |              |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                                  |           | 4            |             | 12/11/95         | 530 | 26.85MG - 180.6MG |
| ORAL; TABLET, SUSTAINED ACTION                             |           | 1            |             |                  |     |                   |
| LACTOSE, HYDROUS   |           |              |             |                  |     |                   |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                     |           | 1            |             |                  |     |                   |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                |           | 1            |             |                  |     |                   |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION               |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE  |           | 45           |             | 03/30/95         | 600 | 20.0MG - 498.65MG |
| ORAL; GRANULE, FOR RECONSTITUTION                          |           | 1            |             |                  |     |                   |
| ORAL; TABLET   |           | 138          |             | 11/30/95         | 510 | 1.0MG - 535.6MG   |
| ORAL; TABLET, COATED                                       |           | 2            |             | 02/25/92         | 600 | 32.0MG - 41.0MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED               |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                                  |           | 9            |             | 12/08/95         | UNK | 12.75MG - 556.0MG |
| ORAL; TABLET, SUSTAINED ACTION                             |           | 6            |             | 01/04/95         | 600 | 58.0MG - 156.8MG  |
| SUBLINGUAL; TABLET   |           | 3            |             | 02/19/88         | 600 | 1.7MG - 11.6MG    |
| VAGINAL; EMULSION, CREAM                                   |           | 1            |             |                  |     |                   |
| LANOLIN  | 008020846 |              |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                                   |           | 2            |             | 04/10/79         | 600 | 2.0%              |
| TOPICAL; LOTION  |           | 4            |             | 12/16/81         | 600 | 0.0014% - 1.0%    |
| TRANSDERMAL; OINTMENT                                      |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM                                   |           | 3            |             | 06/09/86         | 600 | 1.0% - 2.0%       |
| LANOLIN ALCOHOLS   | 008013341 |              |             |                  |     |                   |
| OPHTHALMIC; OINTMENT                                       |           | 3            |             | 12/01/89         | UNK | 10.0%             |
| TOPICAL; EMULSION, CREAM                                   |           | 16           |             | 10/29/93         | UNK | 2.0% - 3.0%       |
| TOPICAL; GEL   |           | 1            |             |                  |     |                   |
| TOPICAL; OINTMENT  |           | 3            |             | 03/23/95         | 600 |                   |
| LANOLIN ALCOHOLS, ACETYLATED                               | 008028986 |              |             |                  |     |                   |
| TOPICAL; SPONGE  |           | 1            |             |                  |     |                   |
| LANOLIN CHOLESTEROLS                                       |           |              |             |                  |     |                   |
| TOPICAL; EMULSION  |           | 1            |             |                  |     |                   |
| LANOLIN NONIONIC DERIVATIVES                               |           |              |             |                  |     |                   |
| OPHTHALMIC; OINTMENT                                       |           | 1            |             |                  |     |                   |
| LANOLIN OIL  | 008038435 |              |             |                  |     |                   |
| OPHTHALMIC; OINTMENT                                       |           | 2            |             | 07/25/94         | 600 | 2.0% - 3.0%       |
| LANOLIN, ANHYDROUS   | 008006540 |              |             |                  |     |                   |
| OPHTHALMIC; OINTMENT                                       |           | 5            |             | 06/17/81         | UNK | 3.0% - 10.0%      |
| TOPICAL; EMULSION, CREAM                                   |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM                                   |           | 1            |             |                  |     |                   |
| LANOLIN, HYDROGENATED                                      | 008031445 |              |             |                  |     |                   |
| TOPICAL; OINTMENT  |           | 3            |             | 12/19/85         | 600 | 0.5% - 10.0%      |
| LAURAMINE OXIDE  |           |              |             |                  |     |                   |
| TOPICAL; SOLUTION  |           | 1            |             |                  |     |                   |
| LAURDIMONIUM HYDROLYZED ANIMAL COLLAGEN                    |           |              |             |                  |     |                   |
| TOPICAL; SHAMPOO   |           | 1            |             |                  |     |                   |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| LAURETH SULFATE<br>TOPICAL; SPONGE                               |           | 1            |             |                  |     |                   |
| LAURETH 23<br>TOPICAL; EMULSION, AEROSOL FOAM                    |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM   |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                   |
| LAURETH 4<br>TOPICAL; LOTION                                     | 009002920 | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION  |           | 1            |             |                  |     |                   |
| LAURIC DIETHANOLAMIDE<br>TOPICAL; LOTION                         | 000120401 | 1            |             |                  |     |                   |
| TOPICAL; SHAMPOO   |           | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION  |           | 1            |             |                  |     |                   |
| TOPICAL; SPONGE  |           | 1            |             |                  |     |                   |
| TOPICAL; SUSPENSION, SHAMPOO                                     |           | 2            |             | 01/10/91         | 600 |                   |
| LAURIC MYRISTIC DIETHANOLAMIDE<br>TOPICAL; EMULSION              |           | 1            |             |                  |     |                   |
| LAURYL SULFATE<br>ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| LECITHIN<br>INHALATION; AEROSOL, METERED                         | 008002435 | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION   |           | 4            |             | 05/24/79         | 520 | 0.3% - 0.6%       |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION                    |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE  |           | 13           |             | 08/29/95         | 600 | 0.5MG - 15.0MG    |
| ORAL; CAPSULE, SUSTAINED ACTION                                  |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                                 |           | 1            |             |                  |     |                   |
| ORAL; TABLET   |           | 2            |             | 05/31/94         | 530 |                   |
| ORAL; TABLET, FILM COATED  |           | 1            |             |                  |     |                   |
| RECTAL; SUPPOSITORY  |           | 2            |             | 05/12/87         | 600 | 1.2MG - 6.5MG     |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                            |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM   |           | 5            |             | 06/09/86         | 600 | 0.3% - 1.0%<br>IG |
| LECITHIN, HYDROGENATED SOY<br>INTRAVENOUS; SUSPENSION, INJECTION |           | 1            |             |                  |     |                   |
| LECITHIN, SOY BEAN<br>INHALATION; AEROSOL, METERED               | 008030760 | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SOFT GELATIN                                      |           | 2            |             | 12/15/86         | 530 | 4.0MG - 20.0MG    |
| VAGINAL; EMULSION, CREAM   |           | 1            |             |                  |     |                   |
| LEMON OIL<br>ORAL; CAPSULE                                       | 008008568 | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SOFT GELATIN                                      |           | 1            |             |                  |     |                   |
| TOPICAL; GEL   |           | 1            |             |                  |     |                   |
| LEVOMENTHOL<br>ORAL; SYRUP                                       | 002216515 | 1            |             |                  |     |                   |
| LIDOFENIN<br>INTRAVENOUS; INJECTION                              | 059160291 | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| LIME OIL                                       | 008008262 | 1            |             |                  |     |                   |
| ORAL; SOLUTION, ELIXIR                         |           |              |             |                  |     |                   |
| LIMONENE, DL-                                  | 000138863 | 1            |             |                  |     |                   |
| TOPICAL; LOTION                                |           |              |             |                  |     |                   |
| LINEAR ALCOHOL ETHYLENE OXIDE ADDUCT           |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION                                |           |              |             |                  |     |                   |
| LUBRITAB                                       |           | 2            |             | 12/22/82         | 600 | 3.45MG - 10.0MG   |
| ORAL; TABLET                                   |           |              |             |                  |     |                   |
| LYSINE   | 000056871 | 1            |             |                  |     |                   |
| IM - IV; INJECTION                             |           |              |             |                  |     |                   |
| IM - IV; POWDER, FOR INJECTION SOLUTION        |           | 1            |             |                  |     |                   |
| MAGNESIUM ALUMINUM SILICATE                    | 001327431 | 1            |             |                  |     |                   |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                   |
| ORAL; GRANULE                                  |           | 3            |             | 12/18/80         | 600 |                   |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                               |           | 26           |             | 03/30/94         | 600 | 0.15% - 2.0%      |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 2            |             | 11/03/70         | UNK |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 07/05/88         | 520 | 8.0MG             |
| RECTAL; SUSPENSION                             |           | 2            |             | 11/17/86         | 600 |                   |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION                                |           | 3            |             | 04/24/85         | UNK | 1.5%              |
| TOPICAL; SHAMPOO                               |           | 2            |             | 08/27/90         | UNK | 0.5%              |
| VAGINAL; OINTMENT                              |           | 1            |             |                  |     |                   |
| MAGNESIUM CARBONATE                            | 000546930 | 1            |             |                  |     |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 8            |             | 02/21/95         | 600 | 5.37MG - 250.0MG  |
| ORAL; TABLET                                   |           | 2            |             | 09/30/59         | 120 |                   |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                   |
| MAGNESIUM CHLORIDE                             | 007791186 | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                       |           | 2            |             | 04/28/95         | 600 | 0.03%             |
| INTRAOCULAR; SOLUTION                          |           | 1            |             |                  |     |                   |
| INTRAPERITONEAL; SOLUTION                      |           | 2            |             | 09/22/95         | UNK |                   |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION         |           | 2            |             |                  |     |                   |
| MAGNESIUM HYDROXIDE                            | 001309428 | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 2            |             | 10/09/91         | 530 | 12.44MG - 450.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           |              |             |                  |     |                   |
| MAGNESIUM NITRATE                              | 010377603 | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                   |
| MAGNESIUM OXIDE                                | 001309484 | 2            |             | 04/25/88         | 600 | 10.0MG            |
| ORAL; CAPSULE                                  |           | 15           |             | 02/09/94         | 510 | 5.0MG - 20.0MG    |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| MAGNESIUM SILICATE                             | 001343880 |              |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                  |
| MAGNESIUM STEARATE                             | 000557040 |              |             |                  |     |                  |
| BUCCAL; TABLET                                 |           | 1            |             |                  |     |                  |
| BUCCAL/SUBLINGUAL; TABLET                      |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 464          |             | 12/29/95         | 600 | 0.003GM          |
| ORAL; CAPSULE, COATED PELLETS                  |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 2            |             | 09/12/89         | 120 |                  |
| ORAL; CAPSULE, HARD GELATIN                    |           | 6            |             | 12/06/95         | 530 | 1.05MG - 7.0MG   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 16           |             | 09/11/95         | 110 | 0.25MG - 100.0MG |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                  |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 1,818        |             | 12/29/95         | 600 |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 17           |             | 09/11/95         | 600 | 1.5MG - 50.0MG   |
| ORAL; TABLET, COATED                           |           | 84           |             | 04/23/95         | 600 | 0.18MG - 40.0MG  |
| ORAL; TABLET, CONTROLLED RELEASE               |           | 1            |             |                  |     |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 14           |             | 11/30/95         | 600 | 0.8MG - 12.0MG   |
| ORAL; TABLET, DISPERSIBLE                      |           | 3            |             | 04/28/95         | 600 |                  |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                      |           | 116          |             | 12/27/95         | 150 | 0.48MG - 10.9MG  |
| ORAL; TABLET, REPEAT ACTION                    |           | 2            |             | 03/31/81         | UNK | 0.7MG - 1.2MG    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 84           |             | 04/28/95         | 600 | 0.3MG - 70.0MG   |
| ORAL; TABLET, UNCOATED, TROCHE                 |           | 1            |             |                  |     |                  |
| ORAL-21; TABLET                                |           | 30           |             | 12/13/93         | 600 | 0.25MG - 1.0MG   |
| ORAL-28; TABLET                                |           | 37           |             | 11/17/95         | 510 | 0.05MG - 75.0MG  |
| SUBLINGUAL; TABLET                             |           | 15           |             | 07/29/88         | 110 | 0.08MG - 1.5MG   |
| TOPICAL; EMULSION, CREAM                       |           | 3            |             | 10/29/93         | UNK |                  |
| VAGINAL; TABLET                                |           | 5            |             | 12/26/91         | 520 | 4.0MG - 17.0MG   |
| MAGNESIUM SULFATE                              | 010034998 |              |             |                  |     |                  |
| ORAL; TABLET                                   |           | 7            |             | 05/15/86         | 600 | 0.5MG - 2.9MG    |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                  |
| MAGNESIUM SULFATE, ANHYDROUS                   | 007487889 |              |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| MAGNESIUM TRISILICATE                          | 001343904 |              |             |                  |     |                  |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                  |
| MALEIC ACID                                    | 000110167 |              |             |                  |     |                  |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION  |           | 1            |             |                  |     |                  |
| IV(INFUSION); INJECTION                        |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| MALEIC ACID                                    | 000110167 | 1            |             |                  |     |                     |
| ORAL; SYRUP                                    |           | 2            |             | 06/28/78         | 510 | 2.0MG               |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| MALIC ACID                                     | 006915157 | 1            |             |                  |     |                     |
| ORAL; SOLUTION                                 |           | 2            |             | 04/27/88         | 510 |                     |
| MALIC ACID, DL-                                |           | 1            |             |                  |     |                     |
| ORAL; SOLUTION                                 |           | 4            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| MALTODEXTRIN                                   |           | 1            |             |                  |     |                     |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 4            |             | 11/05/92         | 600 |                     |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                     |
| MALTOL   | 000118718 | 1            |             |                  |     |                     |
| ORAL; CONCENTRATE                              |           | 4            |             | 10/31/93         | 600 |                     |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                     |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                     |
| MALTOLDEXTRIN                                  | 009050366 | 1            |             |                  |     |                     |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                     |
| MALTOSE  | 000069794 | 1            |             |                  |     |                     |
| ORAL; SOLUTION                                 |           | 2            |             | 04/22/70         | 510 |                     |
| MANNITOL                                       | 000069658 | 1            |             |                  |     |                     |
| IM - IV; INJECTION                             |           | 1            |             |                  |     |                     |
| IM - IV; POWDER, FOR INJECTION SOLUTION        |           | 1            |             |                  |     |                     |
| IM - SC; POWDER, FOR INJECTION SOLUTION        |           | 3            |             | 01/21/94         | 510 |                     |
| INTRAMUSCULAR; INJECTION                       |           | 2            |             | 10/17/85         | 510 |                     |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION  |           | 12           |             | 12/24/91         | 510 | 10.0%               |
| INTRAVENOUS; INJECTION                         |           | 12           |             | 11/29/95         | 600 | 100.0MG             |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 5            |             | 02/16/89         | 600 | 2.0% - 10.0%        |
| IV(INFUSION); INJECTION                        |           | 11           |             | 09/20/95         | 180 | 37.0MG - 1500.0MG   |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 3            |             | 09/22/93         | UNK |                     |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION         |           | 4            |             | 11/04/93         | UNK | 4.05% - 4.6%        |
| OPHTHALMIC; SOLUTION                           |           | 2            |             | 12/30/94         | UNK | 4.5%                |
| OPHTHALMIC; SUSPENSION                         |           | 4            |             | 03/30/89         | 600 | 65.6MG - 283.1MG    |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                     |
| ORAL; GRANULE, EFFERVESCENT                    |           | 1            |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 5            |             | 08/06/84         | 520 | 4.0% - 4.188%       |
| ORAL; TABLET                                   |           | 30           |             | 12/05/94         | 120 | 5.0MG - 302.8MG     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 9            |             | 09/11/95         | 600 | 75.0MG - 600.0MG    |
| ORAL; TABLET, COATED                           |           | 2            |             | 02/11/82         | 120 | 25.8MG - 177.7MG    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 4            |             | 11/18/94         | UNK | 110.0MG - 392.2MG   |
| SUBCUTANEOUS; INJECTION                        |           | 1            |             |                  |     |                     |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION   |           | 4            |             | 05/25/95         | 510 |                     |
| SUBLINGUAL; TABLET                             |           | 6            |             | 02/26/88         | 600 | 10.0MG - 143.4475MG |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                     | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| MANNOSE, D-<br>ORAL; TABLET   | 000530267 | 1            |             |                  |     |                  |
| MEBROFENIN<br>INTRAVENOUS; INJECTION                                | 078266065 | 1            |             |                  |     |                  |
| MEDICAL ANTIFOAM EMULSION C<br>ORAL; SUSPENSION                     |           | 6            |             | 03/18/87         | 600 | 0.08%            |
| ORAL; TABLET  |           | 1            |             |                  |     | 3                |
| MEDICAL ANTIFORM A-F EMULSION<br>TOPICAL; EMULSION, CREAM           |           | 1            |             |                  |     |                  |
| MEDRONATE DISODIUM<br>INTRAVENOUS; INJECTION                        | 025681894 | 1            |             |                  |     |                  |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                         |           | 1            |             |                  |     |                  |
| MEDRONIC ACID<br>INTRAVENOUS; INJECTION                             | 001984152 | 3            |             | 02/17/81         | 160 |                  |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                         |           | 1            |             |                  |     |                  |
| MEGLUMINE<br>INTRA-ARTERIAL; INJECTION                              | 006284408 | 3            |             | 07/26/85         | 160 |                  |
| INTRA-ARTICULAR; INJECTION  |           | 1            |             |                  |     |                  |
| INTRACARDIAC; INJECTION   |           | 2            |             | 07/26/85         | 160 |                  |
| INTRADISCAL; INJECTION  |           | 1            |             |                  |     |                  |
| INTRAUTERINE; INJECTION   |           | 1            |             |                  |     |                  |
| INTRAUTERINE; SOLUTION  |           | 1            |             |                  |     |                  |
| INTRAVENOUS; INJECTION  |           | 4            |             | 06/02/88         | 160 | 0.039%           |
| IV(INFUSION); INJECTION   |           | 1            |             |                  |     |                  |
| PERIARTICULAR; INJECTION  |           | 1            |             |                  |     |                  |
| URETERAL; SOLUTION  |           | 1            |             |                  |     |                  |
| MENTHOL<br>DENTAL; SOLUTION   | 000089781 | 1            |             |                  |     |                  |
| INHALATION; AEROSOL, METERED  |           | 2            |             | 12/28/84         | UNK | 0.02%            |
| ORAL; AEROSOL   |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE   |           | 1            |             |                  |     |                  |
| ORAL; CONCENTRATE   |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                                    |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION  |           | 2            |             | 12/22/94         | 600 |                  |
| ORAL; SUSPENSION  |           | 3            |             | 01/26/84         | 600 | 0.003%           |
| ORAL; SYRUP   |           | 11           |             | 02/21/85         | 600 | 0.01%            |
| ORAL; TABLET  |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION   |           | 3            |             | 04/29/82         | 600 | 0.05001%         |
| METAPHOSPHORIC ACID<br>IV(INFUSION); INJECTION                      | 013478983 | 1            |             |                  |     |                  |
| METHACRYLIC ACID COPOLYMER<br>ORAL; CAPSULE, ENTERIC COATED PELLETS |           | 2            |             | 05/10/95         | 180 |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                                     |           | 1            |             |                  |     |                  |
| ORAL; GRANULE, ENTERIC COATED                                       |           | 1            |             |                  |     |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                        |           | 4            |             | 06/19/95         | 520 | 19.5MG - 48.65MG |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| METHANESULFONIC ACID<br>IM - IV; INJECTION                              | 000075752 | 1            |             |                  |     |                  |
| METHIONINE<br>ORAL; TABLET  | 000063683 | 1            |             |                  |     |                  |
| METHYL ACRYLATE - METHYL METHACRYLATE<br>ORAL; TABLET, SUSTAINED ACTION |           | 1            |             |                  |     |                  |
| METHYL BORONIC ACID<br>INTRAVENOUS; INJECTION                           |           | 1            |             |                  |     |                  |
| METHYL GLUCETH-120 DIOLEATE<br>TOPICAL; SHAMPOO                         |           | 1            |             |                  |     |                  |
| METHYL HYDROXYETHYL CELLULOSE<br>ORAL; TABLET                           |           | 2            |             | 06/02/87         | 600 | 12.0MG - 24.0MG  |
| METHYL LAURATE<br>TRANSDERMAL; FILM, CONTROLLED RELEASE                 |           | 1            |             |                  |     |                  |
| METHYL SALICYLATE<br>TOPICAL; GEL                                       | 000119368 | 1            |             |                  |     |                  |
| METHYL STEARATE<br>TOPICAL; EMULSION, CREAM                             | 000112618 | 1            |             |                  |     |                  |
| VAGINAL; EMULSION, CREAM  |           | 1            |             |                  |     |                  |
| METHYLATED SPIRITS<br>ORAL; CAPSULE                                     |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED  |           | 1            |             |                  |     |                  |
| METHYLCELLULOSE<br>INTRAMUSCULAR; INJECTION                             | 009004675 | 2            |             | 07/07/83         | 600 | 0.03%            |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                                  |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION  |           | 3            |             | 08/24/12         | 600 | 0.1641% - 0.5%   |
| ORAL; CAPSULE   |           | 4            |             | 12/04/85         | 600 | 1.0MG - 6.04MG   |
| ORAL; POWDER, FOR RECONSTITUTION  |           | 4            |             | 04/18/91         | 600 | 0.08% - 0.1%     |
| ORAL; SUSPENSION  |           | 3            |             | 12/16/93         | 180 |                  |
| ORAL; TABLET  |           | 74           |             | 10/30/92         | 600 | 0.756MG - 55.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                          |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED  |           | 7            |             | 01/26/84         | 510 | 0.29MG - 30.0MG  |
| ORAL; TABLET, FILM COATED   |           | 15           |             | 05/09/88         | 600 | 2.3MG - 21.0MG   |
| ORAL; TABLET, SUSTAINED ACTION  |           | 2            |             | 08/21/92         | UNK | 3.0MG            |
| ORAL-28; TABLET   |           | 2            |             | 11/17/95         | 510 | 12.0MG - 15.0MG  |
| SUBLINGUAL; TABLET  |           | 2            |             | 07/07/80         | 600 |                  |
| TOPICAL; EMULSION   |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION   |           | 2            |             |                  |     |                  |
| VAGINAL; EMULSION, CREAM  |           | 1            |             | 04/24/85         | UNK | 0.2% - 1.5%      |
| METHYLCELLULOSE 400<br>OPHTHALMIC; SOLUTION                             |           | 1            |             |                  |     |                  |
| METHYLCHLOROISOTHIAZOLINONE<br>TOPICAL; EMULSION, CREAM                 | 026172554 | 1            |             |                  |     |                  |
| TOPICAL; LOTION   |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| METHYLENE BLUE<br>INTRAVENOUS; INJECTION          | 000061734 | 1            |             |                  |     |                    |
| METHYLISOTHIAZOLINONE<br>TOPICAL; EMULSION, CREAM | 002682204 | 1            |             |                  |     |                    |
| METHYLPARABEN<br>TOPICAL; LOTION                  |           | 1            |             |                  |     |                    |
| METHYLPARABEN<br>CAUDAL BLOCK; INJECTION          | 000099763 | 4            |             | 03/03/87         | 600 | 0.1%               |
| EPIDURAL; INJECTION                               |           | 9            |             | 03/03/87         | 600 | 0.1%               |
| IM - IV - SC; INJECTION                           |           | 26           |             | 04/11/89         | 600 | 0.15% - 0.2%       |
| IM - IV; INJECTION                                |           | 37           |             | 11/27/91         | 600 | 0.065% - 0.2%      |
| IM - SC; INJECTION                                |           | 2            |             | 06/10/87         | 510 | 0.1% - 0.15%       |
| INHALATION; SOLUTION                              |           | 5            |             | 06/30/81         | 600 | 0.0249934% - 0.07% |
| INTRA-ARTICULAR; INJECTION                        |           | 3            |             | 06/19/80         | 600 | 0.15%              |
| INTRABURSAL; INJECTION                            |           | 1            |             |                  |     |                    |
| INTRADERMAL; INJECTION                            |           | 1            |             |                  |     |                    |
| INTRALESIONAL; INJECTION                          |           | 3            |             | 06/19/80         | 600 | 0.15%              |
| INTRAMUSCULAR; INJECTION                          |           | 31           |             | 02/25/93         | 600 | 0.09% - 0.18%      |
| INTRASYNOVIAL; INJECTION                          |           | 2            |             | 03/01/77         | UNK | 0.15%              |
| INTRAVENOUS; INJECTION                            |           | 23           |             | 12/20/91         | UNK | 0.05% - 0.18%      |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION       |           | 1            |             |                  |     |                    |
| IRRIGATION; SOLUTION                              |           | 1            |             |                  |     |                    |
| IV - SC; INJECTION                                |           | 2            |             | 12/05/85         | 180 | 0.15% - 0.18%      |
| IV(INFUSION); INJECTION                           |           | 26           |             | 03/25/94         | 160 | 0.005% - 0.18%     |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION      |           | 1            |             |                  |     |                    |
| NASAL; SOLUTION                                   |           | 2            |             | 05/18/70         | 510 | 0.033%             |
| NERVE BLOCK; INJECTION                            |           | 32           |             | 06/21/88         | 600 | 0.05% - 0.101%     |
| OPHTHALMIC; OINTMENT                              |           | 8            |             | 08/31/95         | 600 | 0.05%              |
| OPHTHALMIC; SOLUTION                              |           | 9            |             | 10/18/88         | 600 | 0.015% - 0.05%     |
| OPHTHALMIC; SUSPENSION                            |           | 2            |             | 12/28/82         | 600 | 0.05%              |
| ORAL; CAPSULE                                     |           | 79           |             | 12/20/95         | 520 | 0.128MG - 1.0MG    |
| ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GEL    |           | 2            |             | 01/29/93         | 600 |                    |
| ORAL; CAPSULE, COATED, SOFT GELATIN               |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, HARD GELATIN                       |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SOFT GELATIN                       |           | 4            |             | 11/22/95         | 150 | 0.22MG - 0.323MG   |
| ORAL; CAPSULE, SUSTAINED ACTION                   |           | 8            |             | 04/25/95         | UNK |                    |
| ORAL; CONCENTRATE                                 |           | 25           |             | 09/28/93         | 600 | 0.005% - 0.2%      |
| ORAL; GRANULE                                     |           | 2            |             | 05/20/88         | 600 |                    |
| ORAL; POWDER, FOR RECONSTITUTION                  |           | 5            |             | 12/31/91         | 520 | 0.02% - 0.1%       |
| ORAL; SOLUTION                                    |           | 46           |             | 11/17/95         | 530 | 0.015% - 0.4%      |
| ORAL; SOLUTION, ELIXIR                            |           | 14           |             | 10/27/92         | 600 | 0.05% - 0.1%       |
| ORAL; SUSPENSION                                  |           | 47           |             | 09/15/95         | 180 | 0.05% - 0.2%       |
| ORAL; SUSPENSION, SUSTAINED ACTION                |           | 1            |             |                  |     |                    |
| ORAL; SYRUP                                       |           | 69           |             | 07/17/95         | 600 | 0.05% - 0.18%      |
| ORAL; TABLET                                      |           | 26           |             | 03/30/94         | 600 | 0.005MG - 0.186MG  |
| ORAL; TABLET, COATED                              |           | 14           |             | 02/25/92         | 600 | 0.01UGM            |
| ORAL; TABLET, FILM COATED                         |           | 3            |             | 12/28/87         | 520 | 0.06MG - 0.23MG    |
| ORAL; TABLET, SUSTAINED ACTION                    |           | 3            |             | 05/22/87         | UNK | 0.17MG             |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| METHYLPARABEN                                | 000099763 |              |             |                  |     |                   |
| ORAL-21; TABLET                              |           | 1            |             |                  |     |                   |
| ORAL-28; TABLET                              |           | 1            |             |                  |     |                   |
| OTIC; SUSPENSION                             |           | 1            |             |                  |     |                   |
| PERIDURAL; INJECTION                         |           | 1            |             |                  |     |                   |
| RECTAL; EMULSION, AEROSOL FOAM               |           | 1            |             |                  |     |                   |
| RECTAL; ENEMA                                |           | 1            |             |                  |     |                   |
| RECTAL; SOLUTION                             |           | 2            |             | 05/27/94         | 600 | 0.18%             |
| RECTAL; SUSPENSION                           |           | 1            |             |                  |     |                   |
| SOFT TISSUE; INJECTION                       |           | 2            |             | 11/17/86         | 600 |                   |
| SUBCUTANEOUS; INJECTION                      |           | 2            |             | 06/19/80         | 600 | 0.15%             |
| TOPICAL; EMULSION, AEROSOL FOAM              |           | 9            |             | 12/19/91         | UNK | 0.1% - 0.15%      |
| TOPICAL; EMULSION, CREAM                     |           | 2            |             | 12/19/79         | 600 | 0.108%            |
| TOPICAL; GEL                                 |           | 65           |             | 10/31/94         | 600 | 0.018% - 0.3%     |
| TOPICAL; GEL, JELLY                          |           | 2            |             | 11/22/88         | UNK | 0.08% - 0.3%      |
| TOPICAL; LOTION                              |           | 2            |             | 04/29/93         | 600 | 0.007%            |
| TOPICAL; OINTMENT                            |           | 15           |             | 12/07/92         | UNK | 0.08% - 0.3%      |
| TOPICAL; SHAMPOO                             |           | 12           |             | 09/30/94         | 600 | 0.02% - 0.4%      |
| TOPICAL; SOLUTION                            |           | 1            |             |                  |     |                   |
| TOPICAL; SUSPENSION, SHAMPOO                 |           | 4            |             | 04/03/85         | 600 | 0.1%              |
| URETERAL; SOLUTION                           |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                   |
| VAGINAL; GEL                                 |           | 12           |             | 12/21/95         | 520 | 0.1% - 0.18%      |
| VAGINAL; SUPPOSITORY                         |           | 1            |             |                  |     |                   |
| METHYLPARABEN SODIUM                         |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION             | 005026620 | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                             |           | 2            |             | 11/17/86         | 600 |                   |
| RECTAL; SUSPENSION                           |           | 1            |             |                  |     |                   |
| MICROCRYSTALLINE WAX                         | 008063089 |              |             |                  |     |                   |
| TOPICAL; GEL                                 |           | 1            |             |                  |     |                   |
| TOPICAL; OINTMENT                            |           | 2            |             | 12/14/90         | UNK | 25.0%             |
| MINERAL OIL                                  | 008012951 |              |             |                  |     |                   |
| DENTAL; PASTE                                |           | 2            |             | 10/01/86         | 600 | 45.795% - 95.0%   |
| OPHTHALMIC; OINTMENT                         |           | 37           |             | 10/30/95         | 600 | 3.0% - 59.5%      |
| OPHTHALMIC; SUSPENSION                       |           | 2            |             | 05/11/88         | 600 |                   |
| ORAL; CAPSULE                                |           | 7            |             | 01/06/75         | 600 | 3.24MG - 5.0MG    |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 1            |             |                  |     |                   |
| ORAL; DROPS                                  |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                 |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                         |           | 13           |             | 09/26/89         | 120 | 0.0002ML - 85.0ML |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 1            |             |                  |     |                   |
| OTIC; OINTMENT                               |           | 1            |             |                  |     |                   |
| OTIC; SUSPENSION                             |           | 1            |             |                  |     |                   |
| TOPICAL; AEROSOL SPRAY                       |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION                              |           | 64           |             | 06/13/95         | 600 | 3.0% - 40.0%      |
|  |           | 9            |             | 12/30/88         | UNK | 1.0% - 16.0%      |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---------------------------------------|-----------|--------------|-------------|------------------|-----|------------------|
| MINERAL OIL                           | 008012951 | 1            |             |                  |     |                  |
| TOPICAL; OIL                          |           | 44           |             |                  |     |                  |
| TOPICAL; OINTMENT                     |           | 1            |             | 03/23/95         | 600 | 0.1% - 95.0%     |
| TOPICAL; PASTE                        |           | 2            |             |                  |     |                  |
| TOPICAL; SUPPOSITORY                  |           | 3            |             | 04/26/93         | 520 |                  |
| TRANSDERMAL; FILM, CONTROLLED RELEASE |           | 8            |             | 10/28/94         | 510 | 2.31MG - 12.4MG  |
| VAGINAL; EMULSION, CREAM              |           | 1            |             | 12/21/95         | 520 | 2.0% - 7.0%      |
| VAGINAL; SUPPOSITORY                  |           |              |             |                  |     |                  |
| MINERAL OIL, LIGHT                    |           |              |             |                  |     |                  |
| OPHTHALMIC; OINTMENT                  |           |              |             |                  |     |                  |
| ORAL; CAPSULE, COATED, SOFT GELATIN   |           | 1            |             |                  |     |                  |
| ORAL; PASTILLE                        |           | 1            |             |                  |     |                  |
| ORAL; TABLET                          |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                  |           | 9            |             | 04/28/89         | 520 | 0.625MG - 7.5MG  |
| ORAL; TABLET, FILM COATED             |           | 2            |             | 02/11/82         | 120 | 0.00015ML        |
| ORAL; TABLET, SUSTAINED ACTION        |           | 2            |             | 08/10/82         | 520 | 1.07MG - 2.494MG |
| RECTAL; SUSPENSION                    |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM              |           | 8            |             |                  |     |                  |
| TOPICAL; LOTION                       |           | 5            |             | 09/28/92         | 600 | 3.0% - 20.0%     |
| TOPICAL; OINTMENT                     |           | 15           |             | 01/24/92         | 600 | 7.0% - 16.0%     |
| TRANSDERMAL; FILM, CONTROLLED RELEASE |           | 2            |             | 03/23/95         | 600 | 4.4% - 23.0%     |
| MONOGLYCERIDE CITRATE                 |           | 2            |             | 09/10/86         | 510 | 19.0MG - 57.0MG  |
| TOPICAL; EMULSION, CREAM              |           |              |             |                  |     |                  |
| MONOGLYCERIDES                        |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION                       |           |              |             |                  |     |                  |
| MULTISTEROL EXTRACT                   |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM              |           |              |             |                  |     |                  |
| MYRISTIC ACID                         |           | 2            |             | 04/10/79         | 600 |                  |
| ORAL; CAPSULE, SUSTAINED ACTION       | 000544638 |              |             |                  |     |                  |
| MYRISTYL ALCOHOL                      |           | 2            |             | 01/28/92         | 600 |                  |
| ORAL; TABLET, SUSTAINED ACTION        | 000112721 |              |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM              |           | 5            |             | 01/04/95         | 600 | 0.58MG - 2.0MG   |
| TOPICAL; LOTION                       |           | 2            |             | 11/20/92         | UNK | 3.0%             |
| MYRISTYL LACTATE                      |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION                       |           |              |             |                  |     |                  |
| MYRISTYL GAMMA-PICOLINIUM CHLORIDE    |           | 1            |             |                  |     |                  |
| INTRA-ARTICULAR; INJECTION            | 002748881 |              |             |                  |     |                  |
| INTRALESIONAL; INJECTION              |           | 3            |             | 03/26/79         | 600 | 0.019%           |
| INTRAMUSCULAR; INJECTION              |           | 3            |             | 03/26/79         | 600 | 0.019%           |
| INTRASYNOVIAL; INJECTION              |           | 4            |             | 03/26/79         | 600 | 0.019% - 0.149%  |
| SOFT TISSUE; INJECTION                |           | 1            |             |                  |     |                  |
|                                       |           | 3            |             | 03/26/79         | 600 | 0.019%           |

## INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| N-(CARBAMOYL-METHOXPOLYETHYLENE GLYCOL 2000)-1,2-DISTEAROYL<br>INTRAVENOUS; SUSPENSION, INJECTION |           | 1            |             |                  |     |                    |
| N-DECYL-METHYL SULFOXIDE<br>TOPICAL; POWDER, FOR RECONSTITUTION                                   |           | 1            |             |                  |     |                    |
| N-2-HYDROXYETHYLPIPERAZINE N'-2'-ETHANESULPHONIC ACID<br>INTRAVENOUS; INJECTION                   |           | 1            |             |                  |     |                    |
| N-3-CHLOROALLYL-METHENAMINE CHLORIDE<br>TOPICAL; EMULSION, CREAM                                  |           | 1            |             |                  |     |                    |
| VAGINAL; EMULSION, CREAM  |           | 1            |             |                  |     |                    |
| N,N-BIS(2-HYDROXYETHYL)STEARAMIDE<br>ORAL; TABLET   | 000093823 | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM  |           | 1            |             |                  |     |                    |
| N,N-DIMETHYL LAURAMINE OXIDE<br>TOPICAL; SOLUTION   |           | 1            |             |                  |     |                    |
| N,N-DIMETHYLACETAMIDE<br>IM - IV; POWDER, FOR INJECTION SOLUTION                                  | 000127195 | 3            |             | 07/24/86         | 600 | 3.5%               |
| IV(INFUSION); INJECTION   |           | 1            |             |                  |     |                    |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION  |           | 1            |             |                  |     |                    |
| NEUTRAL OIL<br>ORAL; AEROSOL  |           | 1            |             |                  |     |                    |
| NIOXIME<br>INTRAVENOUS; INJECTION   | 000492999 | 1            |             |                  |     |                    |
| NIPASTAT<br>ORAL; TABLET  |           | 1            |             |                  |     |                    |
| NITRIC ACID<br>INHALATION; AEROSOL, METERED   | 007697372 | 1            |             |                  |     |                    |
| IV(INFUSION); INJECTION   |           | 2            |             | 05/23/84         | 600 | 0.856% - 1.67%     |
| TOPICAL; EMULSION, CREAM  |           | 4            |             | 10/26/94         | 600 |                    |
| VAGINAL; EMULSION, CREAM  |           | 1            |             |                  |     |                    |
| NON-PAREIL SEED<br>ORAL; CAPSULE  |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, COATED PELLETS   |           | 14           |             | 09/11/92         | 530 | 16.942MG - 299.9MG |
| ORAL; CAPSULE, SUSTAINED ACTION   |           | 1            |             |                  |     |                    |
| ORAL; TABLET  |           | 40           |             | 05/29/90         | 110 | 16.21MG - 823.5MG  |
| ORAL; TABLET, SUSTAINED ACTION  |           | 1            |             |                  |     |                    |
| NONOXYNOL<br>OPHTHALMIC; SOLUTION   | 026027383 | 3            |             | 06/25/86         | 600 | 70.2MG - 157.5MG   |
| NONOXYNOL-15<br>TOPICAL; SOLUTION   | 026027383 | 1            |             |                  |     |                    |
| TOPICAL; SPONGE   |           | 1            |             |                  |     |                    |
| NUTMEG OIL, EXPRESSED<br>ORAL; SOLUTION, ELIXIR   | 008007123 | 1            |             |                  |     |                    |
| OATMEAL<br>TOPICAL; SHAMPOO   |           | 1            |             |                  |     |                    |
| OCTADECENE-1/MALEIC ACID COPOLYMER<br>TOPICAL; LOTION   |           | 1            |             |                  |     |                    |
| OCTOXYNOL<br>TOPICAL; SOLUTION  | 009002931 | 1            |             |                  |     |                    |
|   |           | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                      | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|--|-----------|--------------|-------------|------------------|-----|---------------|
| OCTOXYNOL-1<br>TOPICAL; SPONGE                       | 009002931 | 1            |             |                  |     |               |
| OCTOXYNOL-40<br>OPHTHALMIC; SOLUTION                 |           | 1            |             |                  |     |               |
| OCTOXYNOL-9<br>TOPICAL; SOLUTION                     | 009002931 | 1            |             |                  |     |               |
| TOPICAL; SPONGE                                      |           | 2            |             | 01/07/87         | 520 |               |
| OCTYLDODECANOL<br>TOPICAL; EMULSION, CREAM           | 005333426 | 4            |             | 08/31/93         | 600 | 5.75%         |
| TOPICAL; LOTION                                      |           | 2            |             | 10/27/89         | UNK | 2.013% - 3.3% |
| TOPICAL; SUPPOSITORY                                 |           | 1            |             |                  |     |               |
| VAGINAL; EMULSION, CREAM                             |           | 4            |             | 12/04/95         | 600 |               |
| VAGINAL; SUPPOSITORY                                 |           | 1            |             |                  |     |               |
| OIL CREAM SODA<br>ORAL; SYRUP                        |           | 1            |             |                  |     |               |
| OLEIC ACID<br>INHALATION; AEROSOL, METERED           | 000112801 | 5            |             | 12/28/95         | 600 | 10.5%         |
| NASAL; AEROSOL, METERED                              |           | 2            |             | 09/30/81         | UNK |               |
| ORAL; TABLET, REPEAT ACTION                          |           | 2            |             | 03/31/81         | UNK | 1.854MG       |
| ORAL; TABLET, SUSTAINED ACTION                       |           | 5            |             | 01/14/94         | UNK | 2.0MG         |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                |           | 1            |             |                  |     |               |
| OLETH-10/OLETH-5<br>TOPICAL; EMULSION, CREAM         |           | 1            |             |                  |     |               |
| TOPICAL; SOLUTION                                    |           | 1            |             |                  |     |               |
| OLETH-2<br>TOPICAL; OIL                              |           | 1            |             |                  |     |               |
| OLEYL OLEATE<br>TOPICAL; OINTMENT                    |           | 1            |             |                  |     |               |
| OLIVE OIL<br>ORAL; CAPSULE                           | 008001250 | 1            |             |                  |     |               |
| ORAL; SOLUTION                                       |           | 1            |             |                  |     |               |
| OPACOAT NA2203<br>ORAL; TABLET                       |           | 1            |             |                  |     |               |
| OPACODE S-1-13001 (ORANGE)<br>ORAL; TABLET           |           | 1            |             |                  |     |               |
| OPACODE S-1-1666 (RED)<br>ORAL; TABLET, FILM COATED  |           | 1            |             |                  |     |               |
| ORAL; TABLET, SUSTAINED ACTION, COATED               |           | 1            |             |                  |     |               |
| OPACODE S-1-4157<br>ORAL; CAPSULE                    |           | 1            |             |                  |     |               |
| OPACODE S-1-4160 (BLUE)<br>ORAL; TABLET              |           | 1            |             |                  |     |               |
| OPACODE S-1-4172 (BLUE)<br>ORAL; TABLET, FILM COATED |           | 1            |             |                  |     |               |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                       | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|---|-------|--------------|-------------|------------------|-----|---------------|
| OPACODE S-1-4172M (BLUE)<br>ORAL; TABLET, FILM COATED |       | 1            |             |                  |     |               |
| OPACODE S-1-7020<br>ORAL; CAPSULE                     |       | 1            |             |                  |     |               |
| OPACODE S-1-7078<br>ORAL; CAPSULE                     |       | 1            |             |                  |     |               |
| OPACODE S-1-7085 (WHITE)<br>ORAL; CAPSULE             |       | 2            |             | 08/18/95         | 600 |               |
| OPACODE S-1-7534 (GRAY)<br>ORAL; TABLET               |       | 1            |             |                  |     |               |
| OPACODE S-1-800HV (BLACK)<br>ORAL; CAPSULE            |       | 1            |             |                  |     |               |
| OPACODE S-1-8025 (BLACK)<br>ORAL; CAPSULE             |       | 1            |             |                  |     |               |
| ORAL; CAPSULE, COATED, SOFT GELATIN                   |       | 1            |             |                  |     |               |
| ORAL; TABLET  |       | 1            |             |                  |     |               |
| OPACODE S-1-8081 (BLACK)<br>ORAL; TABLET              |       | 2            |             | 09/19/86         | 600 |               |
| OPACODE S-1-8090 (BLACK)<br>ORAL; CAPSULE             |       | 4            |             | 04/29/87         | 600 |               |
| ORAL; TABLET  |       | 3            |             | 06/19/95         | 180 | 0.4MG - 0.6MG |
| ORAL; TABLET, COATED                                  |       | 4            |             | 12/23/94         | 600 | 0.4MG - 2.4MG |
| ORAL; TABLET, FILM COATED                             |       | 1            |             |                  |     |               |
| OPACODE S-1-8092 (BLACK)<br>ORAL; CAPSULE             |       | 3            |             | 04/22/88         | 600 |               |
| OPACODE S-1-8093 (BLACK)<br>ORAL; TABLET              |       | 1            |             |                  |     |               |
| OPACODE S-1-8095<br>ORAL; TABLET, FILM COATED         |       | 1            |             |                  |     |               |
| OPACODE S-1-8100-HV (BLACK)<br>ORAL; CAPSULE          |       | 2            |             | 07/03/95         | 600 |               |
| ORAL; TABLET  |       | 1            |             |                  |     |               |
| ORAL; TABLET, SUSTAINED ACTION                        |       | 1            |             |                  |     |               |
| OPACODE S-1-8105 (BLACK)<br>ORAL; TABLET              |       | 1            |             |                  |     |               |
| OPACODE S-1-8106 (BLACK)<br>ORAL; TABLET              |       | 4            |             | 05/31/94         | 530 |               |
| ORAL; TABLET, SUSTAINED ACTION                        |       | 1            |             |                  |     |               |
| OPACODE S-1-8114 (BLACK)<br>ORAL; CAPSULE             |       | 1            |             |                  |     |               |
| OPACODE S-1-8115 (BLACK)<br>ORAL; CAPSULE             |       | 3            |             | 09/09/93         | 120 |               |
| OPACODE S-1-9009 (BROWN)<br>ORAL; TABLET, COATED      |       | 1            |             |                  |     |               |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-------|--------------|-------------|------------------|-----|-----------------|
| OPADRY                                       |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY (BROWN)                               |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 3            |             | 10/15/86         | 600 | 17.0MG - 25.5MG |
| OPADRY (CLEAR)                               |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 2            |             | 03/20/95         | 600 | 11.0MG - 15.0MG |
| OPADRY (WHITE)                               |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 3            |             | 11/30/95         | 600 | 6.57MG - 9.0MG  |
| ORAL; TABLET, FILM COATED                    |       | 2            |             | 02/16/95         | 600 | 19.5MG - 27.7MG |
| OPADRY II Y-19-7483 (CLEAR)                  |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 3            |             |                  |     |                 |
| OPADRY II Y-22-7719 (WHITE)                  |       | 2            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                    |       | 1            |             |                  |     |                 |
| OPADRY OY-S-28924 (WHITE)                    |       | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                    |       | 1            |             |                  |     |                 |
| OPADRY Y-S-17191 (BROWN)                     |       | 1            |             |                  |     |                 |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |       | 1            |             |                  |     |                 |
| OPADRY Y-1-1518 (PINK)                       |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-1-2102 (YELLOW)                     |       | 1            |             |                  |     |                 |
| ORAL; TABLET, COATED                         |       | 1            |             |                  |     |                 |
| OPADRY Y-1-2132 (YELLOW)                     |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-1-2605 (BEIGE)                      |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-1-3211 (GREEN)                      |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION               |       | 1            |             |                  |     |                 |
| OPADRY Y-1-4205 (BLUE)                       |       | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                    |       | 1            |             |                  |     |                 |
| OPADRY Y-1-4234 (BLUE)                       |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 3            |             | 02/01/88         | 600 |                 |
| OPADRY Y-1-7000 (WHITE)                      |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-1-7000B (WHITE)                     |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-1-7006 (BLUE)                       |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-22-1452S (PINK)                     |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-5-1244 (PINK)                       |       | 1            |             |                  |     |                 |
| ORAL; TABLET                                 |       | 1            |             |                  |     |                 |
| OPADRY Y-5-12584 (YELLOW)                    |       | 1            |             |                  |     |                 |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |       | 1            |             |                  |     |                 |

## INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-------|--------------|-------------|------------------|-----|--------------------|
| OPADRY Y-5-14530A (PINK)<br>ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |       | 1            |             |                  |     |                    |
| OPADRY Y-5-1727 (RED)<br>ORAL; TABLET                                    |       | 3            |             | 10/16/87         | 600 | 7.0MG              |
| OPADRY Y-5-2028 (YELLOW)<br>ORAL; TABLET                                 |       | 3            |             | 02/15/89         | 600 |                    |
| OPADRY Y-5-2042 (YELLOW)<br>ORAL; TABLET                                 |       | 1            |             |                  |     |                    |
| OPADRY Y-5-2312 (YELLOW)<br>ORAL; TABLET                                 |       | 1            |             |                  |     |                    |
| OPADRY Y-5-2360 (ORANGE)<br>ORAL; TABLET                                 |       | 2            |             | 12/21/87         | 600 | 7.0MG - 14.0MG     |
| OPADRY Y-5-2450 (ORANGE)<br>ORAL; TABLET                                 |       | 3            |             | 07/14/87         | 600 | 14.07MG - 20.895MG |
| OPADRY Y-5-2451 (ORANGE)<br>ORAL; TABLET, FILM COATED                    |       | 3            |             | 08/30/83         | 600 | 3.0MG - 7.875MG    |
| OPADRY Y-5-2451 (ORANGE)<br>ORAL; TABLET                                 |       | 1            |             |                  |     |                    |
| OPADRY Y-5-2646 (BEIGE)<br>ORAL; TABLET                                  |       | 1            |             |                  |     |                    |
| OPADRY Y-5-3140 (GREEN)<br>ORAL; TABLET                                  |       | 1            |             |                  |     |                    |
| OPADRY Y-5-3296 (GREEN)<br>ORAL; TABLET                                  |       | 1            |             |                  |     | .4MG               |
| OPADRY Y-5-4129 (BLUE)<br>ORAL; TABLET                                   |       | 2            |             | 11/27/87         | 600 | 7.0MG              |
| OPADRY Y-5-4270 (BLUE)<br>ORAL; TABLET                                   |       | 1            |             |                  |     |                    |
| OPADRY Y-5-4287 (BLUE)<br>ORAL; TABLET                                   |       | 1            |             |                  |     |                    |
| OPADRY Y-5-7058 (WHITE)<br>ORAL; TABLET                                  |       | 1            |             |                  |     |                    |
| OPADRY Y-5-7058 (WHITE)<br>ORAL; TABLET, COATED                          |       | 4            |             | 10/03/77         | 600 | 2.0MG - 3.0MG      |
| OPADRY Y-5-7068 (WHITE)<br>ORAL; TABLET                                  |       | 9            |             | 11/30/95         | 600 | 1.5MG - 22.4MG     |
| OPADRY Y-5-7068 (WHITE)<br>ORAL; TABLET, COATED                          |       | 6            |             | 06/20/88         | 600 | 1.9MG - 21.0MG     |
| OPADRY Y-5-7068 (WHITE)<br>ORAL; TABLET, CONTROLLED RELEASE              |       | 1            |             |                  |     |                    |
| OPADRY Y-5-7072 (WHITE)<br>ORAL; TABLET                                  |       | 3            |             | 03/28/88         | 600 | 504.0GM            |
| OPADRY Y-5-7411 (PURPLE)<br>ORAL; TABLET                                 |       | 1            |             |                  |     |                    |
| OPADRY Y-5-8050 (BLACK)<br>ORAL; TABLET                                  |       | 3            |             | 10/16/87         | 600 | 7.0MG              |
| OPADRY Y-5-9006 (BROWN)<br>ORAL; TABLET                                  |       | 2            |             | 12/22/88         | 600 | 8.0MG              |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                  | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-------|--------------|-------------|------------------|-----|--------------------|
| OPADRY YS-1-11051 (GREEN)<br>ORAL; TABLET                        |       | 1            |             |                  |     |                    |
| ORAL; TABLET, COATED   |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1107 (GREEN)<br>ORAL; TABLET, FILM COATED            |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1252 (PINK)<br>ORAL; TABLET, FILM COATED             |       | 2            |             | 03/26/93         | 110 | 3.5MG - 4.5MG      |
| OPADRY YS-1-12525-A (YELLOW)<br>ORAL; TABLET, CONTROLLED RELEASE |       | 1            |             |                  |     |                    |
| OPADRY YS-1-12529 (YELLOW)<br>ORAL; TABLET, FILM COATED          |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1288 (PINK)<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1298 (PINK)<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1441G<br>ORAL; TABLET, FILM COATED                   |       | 1            |             |                  |     |                    |
| OPADRY YS-1-14518A (PINK)<br>ORAL; TABLET, CONTROLLED RELEASE    |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1510 (PINK)<br>ORAL; TABLET                          |       | 3            |             | 05/15/90         | 600 | 4.2MG              |
| OPADRY YS-1-1528 (PINK)<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1724 (RED)<br>ORAL; TABLET                           |       | 2            |             | 11/23/87         | 600 | 9.221MG - 18.566MG |
| OPADRY YS-1-18034 (WHITE)<br>ORAL; TABLET, FILM COATED           |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1846 (RED)<br>ORAL; TABLET                           |       | 1            |             |                  |     |                    |
| OPADRY YS-1-1847 (RED)<br>ORAL; TABLET                           |       | 1            |             |                  |     |                    |
| OPADRY YS-1-2013 (YELLOW)<br>ORAL; TABLET                        |       | 1            |             |                  |     |                    |
| OPADRY YS-1-2065<br>ORAL; CAPLET                                 |       | 1            |             |                  |     |                    |
| OPADRY YS-1-2074 (YELLOW)<br>ORAL; TABLET, FILM COATED           |       | 1            |             |                  |     |                    |
| OPADRY YS-1-2122 (YELLOW)<br>ORAL; TABLET                        |       | 2            |             | 09/24/86         | 600 |                    |
| OPADRY YS-1-2134 (YELLOW)<br>ORAL; TABLET                        |       | 1            |             |                  |     |                    |
| OPADRY YS-1-2136 (YELLOW)<br>ORAL; TABLET                        |       | 1            |             |                  |     |                    |
| OPADRY YS-1-2167 (YELLOW)<br>ORAL; TABLET, SUSTAINED ACTION      |       | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-------|--------------|-------------|------------------|-----|-----------------|
| OPADRY YS-1-2186 (YELLOW)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2465<br>ORAL; TABLET                           |       | 3            |             | 10/07/88         | 600 |                 |
| OPADRY YS-1-2522 (ORANGE)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2526 (ORANGE)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2527 (ORANGE)<br>ORAL; TABLET                  |       | 10           |             | 11/12/86         | 600 |                 |
| OPADRY YS-1-2534<br>ORAL; TABLET, SUSTAINED ACTION         |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2546 (ORANGE)<br>ORAL; TABLET, FILM COATED     |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2546 (ORANGE)<br>ORAL; TABLET, FILM COATED     |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2558 (ORANGE)<br>ORAL; TABLET, FILM COATED     |       | 3            |             | 05/31/95         | 600 | 9.5MG - 14.0MG  |
| OPADRY YS-1-2563 (ORANGE)<br>ORAL; TABLET, FILM COATED     |       | 1            |             | 11/27/89         | 110 | 10.0MG - 15.0MG |
| OPADRY YS-1-2563 (ORANGE)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2604 (BEIGE)<br>ORAL; TABLET                   |       | 2            |             | 04/30/84         | 600 | 7.5MG           |
| OPADRY YS-1-2612 (BEIGE)<br>ORAL; TABLET, FILM COATED      |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2612 (BEIGE)<br>ORAL; TABLET, SUSTAINED ACTION |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2635 (TAN)<br>ORAL; TABLET, SUSTAINED ACTION   |       | 1            |             |                  |     |                 |
| OPADRY YS-1-2669 (RUST)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPADRY YS-1-3105 (GREEN)<br>ORAL; TABLET                   |       | 2            |             | 03/21/86         | 600 | 15.0MG          |
| OPADRY YS-1-3130 (GREEN)<br>ORAL; TABLET, COATED           |       | 2            |             | 05/17/94         | 600 | 0.4MG - 36.0MG  |
| OPADRY YS-1-3146 (GREEN)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                 |
| OPADRY YS-1-3166 (GREEN)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                 |
| OPADRY YS-1-4018 (BLUE)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPADRY YS-1-4112 (BLUE)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                 |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                    | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-------|--------------|-------------|------------------|-----|--------------------|
| OPADRY YS-1-4215<br>ORAL; TABLET                                   |       | 2            |             | 01/11/94         | UNK |                    |
| OPADRY YS-1-4216<br>ORAL; TABLET                                   |       | 1            |             |                  |     |                    |
| OPADRY YS-1-4221 (BLUE)<br>ORAL; TABLET                            |       | 2            |             | 12/10/86         | 600 |                    |
| OPADRY YS-1-4229 (BLUE)<br>ORAL; TABLET                            |       | 1            |             |                  |     |                    |
| OPADRY YS-1-4236 (BLUE)<br>ORAL; TABLET                            |       | 1            |             |                  |     |                    |
| OPADRY YS-1-4245 (BLUE)<br>ORAL; TABLET, FILM COATED               |       | 1            |             |                  |     |                    |
| OPADRY YS-1-4298 (BLUE)<br>ORAL; TABLET, FILM COATED               |       | 1            |             |                  |     |                    |
| OPADRY YS-1-4710<br>ORAL; TABLET                                   |       | 3            |             | 05/19/86         | 600 | 4.0MG              |
| OPADRY YS-1-6275 (ORANGE)<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPADRY YS-1-6312 (YELLOW)<br>ORAL; TABLET, FILM COATED             |       | 1            |             |                  |     |                    |
| OPADRY YS-1-6357 (YELLOW)<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPADRY YS-1-7002 (WHITE)<br>ORAL; TABLET, FILM COATED              |       | 1            |             |                  |     |                    |
| OPADRY YS-1-7003 (WHITE)<br>ORAL; TABLET                           |       | 38           |             | 09/29/95         | 600 | 0.4MG - 27.9MG     |
| ORAL; TABLET, FILM COATED  |       | 7            |             | 09/14/95         | 110 | 3.0MG - 9.0MG      |
| ORAL; TABLET, SUSTAINED ACTION                                     |       | 2            |             | 11/18/94         | UNK | 22.42MG            |
| OPADRY YS-1-7006 (CLEAR)<br>ORAL; TABLET                           |       | 51           |             | 11/30/95         | 600 |                    |
| ORAL; TABLET, COATED   |       | 9            |             | 06/23/95         | 600 |                    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                       |       | 5            |             | 11/30/95         | 600 | 0.0005GM           |
| ORAL; TABLET, FILM COATED  |       | 14           |             | 09/29/95         | 600 | 0.2MG - 11.0MG     |
| OPADRY YS-1-7027 (WHITE)<br>ORAL; TABLET, SUSTAINED ACTION, COATED |       | 1            |             |                  |     |                    |
| OPADRY YS-1-7444G (WHITE)<br>ORAL; TABLET, COATED                  |       | 2            |             | 05/17/94         | 600 | 11.0MG - 22.0MG    |
| OPADRY YS-1-7507 (GREY)<br>ORAL; TABLET                            |       | 2            |             | 11/23/87         | 600 | 9.443MG - 19.057MG |
| ORAL; TABLET, FILM COATED  |       | 1            |             |                  |     |                    |
| OPADRY YS-1-7552 (GREY)<br>ORAL; TABLET                            |       | 2            |             | 03/09/87         | 600 | 7.3MG              |
| OPADRY YS-1-7706G (WHITE)<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-------|--------------|-------------|------------------|-----|-------------------|
| OPADRY YS-1-8325 (BEIGE)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                   |
| OPADRY YS-1-8345G (BEIGE)<br>ORAL; TABLET, FILM COATED     |       | 1            |             |                  |     |                   |
| OPADRY YS-1-8619 (ORANGE)<br>ORAL; TABLET, FILM COATED     |       | 1            |             |                  |     |                   |
| OPADRY YS-1-89193 (CLEAR)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                   |
| OPADRY YS-1-9012 (BROWN)<br>ORAL; TABLET                   |       | 4            |             | 12/08/87         | 600 | 12.6MG            |
| OPADRY YS-2-7013 (CLEAR)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                   |
| OPADRY YS-2-7063 (WHITE)<br>ORAL; TABLET, COATED           |       | 1            |             |                  |     |                   |
| OPADRY YS-2-7063 (WHITE)<br>ORAL; TABLET, FILM COATED      |       | 2            |             | 09/14/95         | 110 | 0.6MG - .7MG      |
| OPADRY YS-2-7063 (WHITE)<br>ORAL; TABLET, SUSTAINED ACTION |       | 1            |             | 04/26/94         | 510 | 19.0MG - 24.0MG   |
| OPADRY YS-3-7011 (CLEAR)<br>ORAL; TABLET                   |       | 24           |             | 05/15/90         | 600 | 0.5MG - 17.2MG    |
| OPADRY YS-3-7031 (CLEAR)<br>ORAL; TABLET                   |       | 5            |             | 09/12/86         | 600 | 2.5MG - 8.0MG     |
| OPADRY YS-3-7413 (CLEAR)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                   |
| OPADRY YS-3-7413 (CLEAR)<br>ORAL; TABLET, COATED           |       | 1            |             |                  |     |                   |
| OPADRY YS-3-7413 (CLEAR)<br>ORAL; TABLET, FILM COATED      |       | 1            |             |                  |     |                   |
| OPADRY YS-5-1296 (PINK)<br>ORAL; TABLET                    |       | 2            |             | 03/25/94         | 600 | 5.775MG - 11.55MG |
| OPADRY YS-5-2170 (YELLOW)<br>ORAL; TABLET                  |       | 2            |             | 02/16/88         | 600 | 6.112MG           |
| OPADRY YS-5-2370 (ORANGE)<br>ORAL; TABLET                  |       | 4            |             | 09/16/83         | 600 |                   |
| OPADRY YS-5-2370 (ORANGE)<br>ORAL; TABLET, FILM COATED     |       | 1            |             |                  |     |                   |
| OPADRY YS-5-7042 (CLEAR)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                   |
| OPADRY YS-5-7068<br>ORAL; TABLET                           |       | 4            |             | 09/29/87         | 600 |                   |
| OPAGLOS CLEAR<br>ORAL; TABLET, COATED                      |       | 1            |             |                  |     |                   |
| OPAGLOS GS 2-0310<br>ORAL; TABLET                          |       | 1            |             |                  |     |                   |
| OPALUX AS 1537 (PINK)<br>ORAL; TABLET, COATED              |       | 1            |             |                  |     |                   |
| OPALUX AS 1589 (PINK)<br>ORAL; TABLET, COATED              |       | 4            |             | 11/19/82         | 600 | 0.022MG - 0.07MG  |
| OPALUX AS 2006 (YELLOW)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-------|--------------|-------------|------------------|-----|-------------------|
| OPALUX AS 2167 (YELLOW)<br>ORAL; TABLET, COATED            |       | 1            |             |                  |     |                   |
| OPALUX AS 2236<br>ORAL; TABLET                             |       | 1            |             |                  |     |                   |
| OPALUX AS 2269 (YELLOW)<br>ORAL; TABLET, COATED            |       | 4            |             | 06/17/77         | 600 | 12.0MG - 22.125MG |
| OPALUX AS 2324 (ORANGE)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                   |
| OPALUX AS 2336 (ORANGE)<br>ORAL; TABLET, COATED            |       | 1            |             |                  |     |                   |
| OPALUX AS 2413<br>ORAL; TABLET                             |       | 1            |             |                  |     |                   |
| OPALUX AS 2498 (ORANGE)<br>ORAL; TABLET, COATED            |       | 1            |             |                  |     |                   |
| OPALUX AS 2512<br>ORAL; TABLET, SUSTAINED ACTION           |       | 2            |             | 12/20/82         | 600 | 0.86MG - 3.0MG    |
| OPALUX AS 2676 SALMON (JASPER RED)<br>ORAL; TABLET         |       | 1            |             |                  |     |                   |
| OPALUX AS 2754<br>ORAL; TABLET, COATED                     |       | 2            |             | 10/21/83         | 600 | 1.1MG - 1.4MG     |
| OPALUX AS 3348-C (GREEN)<br>ORAL; TABLET, SUSTAINED ACTION |       | 1            |             |                  |     |                   |
| OPALUX AS 3391 (GREEN)<br>ORAL; TABLET                     |       | 1            |             |                  |     |                   |
| OPALUX AS 4208-A (BLUE)<br>ORAL; TABLET, COATED            |       | 1            |             |                  |     |                   |
| OPALUX AS 4270 (BLUE)<br>ORAL; TABLET, SUSTAINED ACTION    |       | 1            |             |                  |     |                   |
| OPALUX AS 5178 (GREEN)<br>ORAL; TABLET, COATED             |       | 4            |             | 11/19/82         | 600 | 4.21MG - 12.632MG |
| OPALUX AS 5203 (GREEN)<br>ORAL; TABLET                     |       | 1            |             |                  |     |                   |
| OPALUX AS 5212 (GREEN)<br>ORAL; TABLET, COATED             |       | 1            |             |                  |     |                   |
| OPALUX AS 7000-B<br>ORAL; TABLET, COATED                   |       | 1            |             |                  |     |                   |
| OPALUX AS 7000-P (WHITE)<br>ORAL; TABLET, COATED           |       | 3            |             | 02/25/92         | 600 | 0.36MG - 4.95MG   |
| OPALUX AS 7535 (GRAY)<br>ORAL; TABLET, COATED              |       | 1            |             |                  |     |                   |
| OPALUX AS 8050-L (BLACK)<br>ORAL; CAPSULE                  |       | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-------|--------------|-------------|------------------|-----|------------------|
| OPALUX AS 9010 (BROWN)<br>ORAL; TABLET, COATED |       | 1            |             |                  |     |                  |
| OPAQUE BLUE 605<br>ORAL; CAPSULE               |       | 1            |             |                  |     |                  |
| OPAQUE BURRGANDY<br>ORAL; CAPSULE              |       | 1            |             |                  |     |                  |
| OPAQUE GRAY<br>ORAL; CAPSULE                   |       | 2            |             | 10/26/90         | 600 | 37.5MG           |
| OPAQUE GREEN<br>ORAL; CAPSULE                  |       | 3            |             | 10/26/90         | 600 | 49.0MG           |
| OPAQUE GREEN 1664<br>ORAL; CAPSULE             |       | 1            |             |                  |     |                  |
| OPAQUE GREEN/FLESH<br>ORAL; CAPSULE            |       | 1            |             |                  |     |                  |
| OPAQUE MAROON 6 DAR<br>ORAL; CAPSULE           |       | 2            |             | 03/20/89         | 600 |                  |
| OPAQUE ORANGE<br>ORAL; CAPSULE                 |       | 1            |             |                  |     |                  |
| OPAQUE PEACH<br>ORAL; CAPSULE                  |       | 1            |             |                  |     |                  |
| OPAQUE PINK BK<br>ORAL; CAPSULE                |       | 1            |             |                  |     |                  |
| OPAQUE PINK 0439<br>ORAL; CAPSULE              |       | 1            |             |                  |     |                  |
| OPAQUE RED<br>ORAL; CAPSULE                    |       | 1            |             |                  |     |                  |
| OPAQUE SWEDISH ORANGE<br>ORAL; CAPSULE         |       | 1            |             |                  |     |                  |
| OPAQUE WHITE<br>ORAL; CAPSULE                  |       | 6            |             | 12/29/95         | 600 | 39.0MG - 62.0MG  |
| OPAQUE WHITE 535<br>ORAL; CAPSULE              |       | 1            |             |                  |     |                  |
| OPAQUE WHITE 536<br>ORAL; CAPSULE              |       | 1            |             |                  |     |                  |
| OPAQUE WHITE 538<br>ORAL; CAPSULE              |       | 1            |             |                  |     |                  |
| OPAQUE YELLOW<br>ORAL; CAPSULE                 |       | 1            |             |                  |     |                  |
| OPASEAL<br>ORAL; TABLET, SUSTAINED ACTION      |       | 2            |             | 05/24/83         | 600 |                  |
| OPASPRAY<br>ORAL; TABLET                       |       | 12           |             | 11/10/88         | 600 | 1.683MG - 6.27MG |
| ORAL; TABLET, FILM COATED                      |       | 5            |             | 05/09/88         | 600 | 0.45MG - 12.0MG  |
| ORAL; TABLET, SUSTAINED ACTION                 |       | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---------------------------------|-------|--------------|-------------|------------------|-----|-----------------|
| OPASPRAY CORAL                  |       | 1            |             |                  |     |                 |
| ORAL; TABLET, COATED            |       | 1            |             |                  |     |                 |
| OPASPRAY GREEN                  |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1230 (PINK)        |       | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION  |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1279               |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1289 (PINK)        |       | 3            |             | 08/12/88         | 600 | 0.6MG - 1.14MG  |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1413 (PINK)        |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1414 (PINK)        |       | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1455 (PINK)        |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1460               |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 2            |             | 08/29/88         | 600 | 2.7MG - 5.39MG  |
| OPASPRAY K-1-1563 (PINK)        |       | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED       |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1573 (LAVENDER)    |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-1584               |       | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION  |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-2013 (YELLOW)      |       | 2            |             | 06/23/89         | 600 | 8.0MG           |
| ORAL; TABLET                    |       | 2            |             | 08/29/88         | 600 | 3.71MG - 4.69MG |
| OPASPRAY K-1-2088               |       | 2            |             |                  |     |                 |
| ORAL; TABLET                    |       | 2            |             |                  |     |                 |
| OPASPRAY K-1-2216-A (YELLOW)    |       | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION  |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-2228 (YELLOW)      |       | 2            |             | 01/09/87         | 600 | 3.0MG - 17.8MG  |
| ORAL; TABLET, SUSTAINED ACTION  |       | 2            |             |                  |     |                 |
| OPASPRAY K-1-2240 (YELLOW)      |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-2275 (YELLOW)      |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-2301 (PEACH)       |       | 5            |             | 08/17/88         | 600 | 0.69MG - 4.7MG  |
| ORAL; TABLET                    |       | 5            |             |                  |     |                 |
| OPASPRAY K-1-2304 (ORANGE)      |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |
| OPASPRAY K-1-2314 (ORANGE)      |       | 1            |             |                  |     |                 |
| ORAL; TABLET                    |       | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                              | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-------|--------------|-------------|------------------|-----|------------------|
| OPASPRAY K-1-2327 (ORANGE)<br>ORAL; TABLET, SUSTAINED ACTION |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2330 (ORANGE)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2335 (ORANGE)<br>ORAL; TABLET, FILM COATED      |       | 2            |             | 02/02/87         | 600 | 0.525MG - 1.05MG |
| OPASPRAY K-1-2406 (ORANGE)<br>ORAL; TABLET, FILM COATED      |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2410 (ORANGE)<br>ORAL; TABLET, FILM COATED      |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2430<br>ORAL; TABLET                            |       | 2            |             | 05/11/84         | 600 | 5.7MG            |
| OPASPRAY K-1-2441 (ORANGE)<br>ORAL; TABLET                   |       | 2            |             | 10/15/85         | 600 | 1.0MG - 4.0MG    |
| OPASPRAY K-1-2473<br>ORAL; TABLET, FILM COATED               |       | 2            |             | 08/11/88         | 600 | 14.0MG - 22.5MG  |
| OPASPRAY K-1-2492<br>ORAL; TABLET                            |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2533 (ORANGE)<br>ORAL; TABLET, SUSTAINED ACTION |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2568 (ORANGE)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2588 (ORANGE)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2621 (BROWN)<br>ORAL; TABLET, FILM COATED       |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2626 (ORANGE)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2656 (BEIGE)<br>ORAL; TABLET, FILM COATED       |       | 2            |             | 11/08/82         | 600 | 0.737MG - 9.08MG |
| OPASPRAY K-1-2670 (TAN)<br>ORAL; TABLET, FILM COATED         |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-2685<br>ORAL; TABLET                            |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-3000<br>ORAL; TABLET                            |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-3147<br>ORAL; TABLET                            |       | 2            |             | 01/23/86         | 600 | 1.9MG - 3.0MG    |
| OPASPRAY K-1-3148 (GREEN)<br>ORAL; TABLET, FILM COATED       |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-3173 (GREEN)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                  |
| OPASPRAY K-1-3178 (GREEN)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-------|--------------|-------------|------------------|-----|--------------------|
| OPASPRAY K-1-3220 (GREEN)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-3227<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-3227<br>ORAL; TABLET, COATED                  |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-3300-A (GREEN)<br>ORAL; TABLET                |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-3300-C (GREEN)<br>ORAL; TABLET                |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-4136 (BLUE)<br>ORAL; TABLET                   |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-4210-A<br>ORAL; TABLET                        |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-4227<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-4235 (BLUE)<br>ORAL; TABLET                   |       | 2            |             | 01/29/85         | 600 | 8.283MG - 15.567MG |
| OPASPRAY K-1-4728<br>ORAL; TABLET                          |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-4743 (LAVENDER)<br>ORAL; TABLET               |       | 2            |             | 11/10/88         | 600 | 2.2MG              |
| OPASPRAY K-1-4748 (PURPLE)<br>ORAL; TABLET, FILM COATED    |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-5024 (RED)<br>ORAL; CAPSULE, SUSTAINED ACTION |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-7000 (WHITE)<br>ORAL; TABLET                  |       | 25           |             | 10/29/92         | UNK | 0.37MG - 22.5MG    |
| OPASPRAY K-1-7000 (WHITE)<br>ORAL; TABLET, COATED          |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-7000 (WHITE)<br>ORAL; TABLET, FILM COATED     |       | 2            |             | 11/20/86         | 510 | 3.96MG             |
| OPASPRAY K-1-70008 (WHITE)<br>ORAL; TABLET                 |       | 4            |             | 12/05/86         | 600 | 7.074MG - 22.4MG   |
| OPASPRAY K-1-9027 (BROWN)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-9039-L (BROWN)<br>ORAL; TABLET                |       | 2            |             | 01/16/84         | 600 | 8.0MG - 12.2MG     |
| OPASPRAY K-1-9039-L (BROWN)<br>ORAL; TABLET, FILM COATED   |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-9080 (BROWN)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                    |
| OPASPRAY K-1-9112 (BROWN)<br>ORAL; TABLET                  |       | 1            |             |                  |     |                    |
| OPASPRAY L-2113<br>ORAL; TABLET                            |       | 1            |             |                  |     |                    |
| OPASPRAY L-3305 (GREEN)<br>ORAL; TABLET                    |       | 1            |             |                  |     |                    |

## INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| OPASPRAY L-3306 (GREEN)<br>ORAL; TABLET                                 |           | 1            |             |                  |     |                  |
| OPASPRAY L-7000 (WHITE)<br>ORAL; TABLET                                 |           | 1            |             |                  |     |                  |
| OPASPRAY M-1-711B (WHITE)<br>ORAL; TABLET                               |           | 1            |             |                  |     |                  |
| OPASPRAY M-1-7111-B<br>ORAL; TABLET                                     |           | 4            |             | 12/16/92         | 120 | 0.92MG - 26.67MG |
| OPASPRAY M-1-7120 (WHITE)<br>ORAL; TABLET, FILM COATED                  |           | 1            |             |                  |     |                  |
| OPASPRAY M-1-7301 (WHITE)<br>ORAL; TABLET, COATED                       |           | 1            |             |                  |     | .2MG             |
| OPASPRAY M-1-8429 (YELLOW)<br>ORAL; TABLET, FILM COATED                 |           | 1            |             |                  |     |                  |
| OPASPRAY WD-1270 (PINK)<br>ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 1            |             |                  |     |                  |
| OPASPRAY 3-1820<br>ORAL; TABLET   |           | 1            |             |                  |     |                  |
| OPASPRAY 3-1830<br>ORAL; TABLET   |           | 1            |             |                  |     |                  |
| OPATINT DD-13009 (ORANGE)<br>ORAL; TABLET                               |           | 1            |             |                  |     |                  |
| OPATINT DD-1800 (WHITE)<br>ORAL; TABLET                                 |           | 1            |             |                  |     |                  |
| ORANGE FLOWER OIL<br>ORAL; TABLET                                       | 008022977 | 1            |             |                  |     |                  |
| ORANGE JUICE<br>ORAL; SUSPENSION  |           | 1            |             |                  |     |                  |
| ORANGE JUICE, SYNTHETIC<br>ORAL; SOLUTION                               |           | 1            |             |                  |     |                  |
| ORANGE OIL<br>ORAL; GRANULE, EFFERVESCENT                               | 008008579 | 1            |             |                  |     |                  |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION, ELIXIR  |           | 7            |             | 12/17/82         | 600 | 0.024%           |
| ORAL; SYRUP   |           | 1            |             |                  |     |                  |
| ORANGE OIL, TERPENELESS<br>ORAL; SUSPENSION                             |           | 2            |             | 11/18/82         | 600 |                  |
| ORAL; SYRUP   |           | 1            |             |                  |     |                  |
| OXIDRONATE SODIUM<br>INTRAVENOUS; INJECTION                             |           | 1            |             |                  |     |                  |
| OXYQUINOLINE<br>INTRAVENOUS; INJECTION                                  | 000148243 | 1            |             |                  |     |                  |
| PALM KERNEL OIL<br>RECTAL; SUPPOSITORY                                  | 008023798 | 1            |             |                  |     |                  |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| PALM KERNEL OIL, HYDROGENATED<br>RECTAL; SUPPOSITORY  | 068990829 | 1            |             |                  |     |                   |
| PALM OIL - SOYBEAN OIL, HYDROGENATED<br>ORAL; CAPSULE |           | 1            |             |                  |     |                   |
| PALM OIL, HYDROGENATED<br>RECTAL; SUPPOSITORY         | 008033292 | 1            |             |                  |     |                   |
| PALMITAMINE OXIDE<br>TOPICAL; SOLUTION                | 007128918 | 1            |             |                  |     |                   |
| PARABENS<br>ORAL; CAPSULE                             |           | 5            |             | 01/27/89         | 510 |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                       |           | 1            |             |                  |     |                   |
| ORAL; DROPS   |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                      |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                                      |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                        |           | 1            |             |                  |     |                   |
| TOPICAL; AEROSOL                                      |           | 1            |             |                  |     |                   |
| PARAFFIN<br>ORAL; TABLET                              | 008002742 | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                        |           | 6            |             | 03/30/95         | 110 | 0.1MG - 150.0MG   |
| TOPICAL; EMULSION, CREAM                              |           | 6            |             | 02/01/89         | 600 | 2.0%              |
| TOPICAL; OINTMENT                                     |           | 2            |             | 12/14/90         | UNK | 8.27%             |
| PARMACOAT 606<br>ORAL; TABLET                         |           | 1            |             |                  |     |                   |
| PEANUT OIL<br>INTRAMUSCULAR; INJECTION                | 008002037 | 2            |             | 06/16/54         | 510 | 70.0%             |
| ORAL; CAPSULE   |           | 4            |             | 10/29/91         | 600 | 205.0MG - 313.8MG |
| TOPICAL; OIL  |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM                              |           | 7            |             | 06/09/86         | 600 | 0.5% - 9.0%       |
| PECTIN<br>DENTAL; PASTE                               | 009000695 | 3            |             | 07/06/87         | 600 | 16.6% - 16.7%     |
| TOPICAL; PASTE  |           | 1            |             |                  |     |                   |
| PEG VEGETABLE OIL<br>IM - SC; INJECTION               | 008051352 | 1            |             |                  |     |                   |
| PEG LICOL-5-OLEATE<br>ORAL; SOLUTION                  |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                              |           | 2            |             | 12/23/82         | UNK | 3.0%              |
| TOPICAL; SUPPOSITORY                                  |           | 2            |             | 04/26/93         | 520 |                   |
| VAGINAL; EMULSION, CREAM                              |           | 3            |             | 01/04/95         | 600 | 3.0%              |
| VAGINAL; SUPPOSITORY                                  |           | 1            |             |                  |     |                   |
| PEGOXOL 7 STEARATE<br>TOPICAL; EMULSION, CREAM        |           | 1            |             |                  |     |                   |
| TOPICAL; SUPPOSITORY                                  |           | 2            |             | 04/26/93         | 520 |                   |
| VAGINAL; EMULSION, CREAM                              |           | 2            |             | 01/04/95         | 600 | 18.0%             |
| VAGINAL; SUPPOSITORY                                  |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| PENTAERYTHRITOL COCOATE<br>TOPICAL; OINTMENT          |           | 1            |             |                  |     |                    |
| PENTETATE CALCIUM TRISODIUM<br>INTRAVENOUS; INJECTION | 012111249 | 2            |             | 11/16/76         | 160 |                    |
| IV(INFUSION); INJECTION                               |           | 1            |             |                  |     |                    |
| PENTETATE PENTASODIUM<br>INTRAVENOUS; INJECTION       |           | 1            |             |                  |     |                    |
| PENTETIC ACID<br>INTRATHECAL; INJECTABLE              | 000067436 | 1            |             |                  |     |                    |
| INTRAVENOUS; INJECTION                                |           | 2            |             | 12/19/90         | 160 | 0.015%             |
| PEPPERMINT<br>DENTAL; SOLUTION                        |           | 1            |             |                  |     |                    |
| ORAL; SOLUTION, ELIXIR                                |           | 1            |             |                  |     |                    |
| PEPPERMINT OIL<br>DENTAL; SOLUTION                    | 008006904 | 1            |             |                  |     |                    |
| ORAL; AEROSOL   |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE   |           | 6            |             | 04/30/92         | 600 | 0.68MG - 1.02MG    |
| ORAL; CAPSULE, SOFT GELATIN                           |           | 2            |             | 02/19/92         | 600 | 0.68MG             |
| ORAL; CONCENTRATE                                     |           | 2            |             | 07/20/88         | 600 | 0.005% - 5.0%      |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                    |
| ORAL; SOLUTION, ELIXIR                                |           | 2            |             | 12/01/81         | 600 | 0.0951%            |
| ORAL; SUSPENSION                                      |           | 8            |             | 12/27/91         | 600 | 0.01% - 10.0%      |
| ORAL; SYRUP   |           | 7            |             | 03/29/84         | UNK | 0.06%              |
| ORAL; TABLET  |           | 5            |             | 11/06/85         | 600 | 0.14MG - 3.5MG     |
| SUBLINGUAL; TABLET                                    |           | 1            |             |                  |     |                    |
| TOPICAL; OINTMENT                                     |           | 1            |             |                  |     |                    |
| PERFUME E-1991<br>TOPICAL; EMULSION, CREAM            |           | 1            |             |                  |     |                    |
| PERFUME GD 5604<br>TOPICAL; EMULSION, CREAM           |           | 1            |             |                  |     |                    |
| PERFUME TANA 90/42 SCBA<br>TOPICAL; LOTION            |           | 1            |             |                  |     |                    |
| PERFUMES<br>TOPICAL; EMULSION, CREAM                  |           | 1            |             |                  |     |                    |
| TOPICAL; LOTION                                       |           | 1            |             |                  |     |                    |
| TOPICAL; OINTMENT                                     |           | 1            |             |                  |     |                    |
| TOPICAL; SHAMPOO                                      |           | 2            |             | 08/31/90         | UNK | 0.2% - 0.25%       |
| TOPICAL; SPONGE                                       |           | 1            |             |                  |     |                    |
| TOPICAL; SUSPENSION, SHAMPOO                          |           | 1            |             |                  |     |                    |
| PETROLATUM<br>OPHTHALMIC; OINTMENT                    | 008009038 | 31           |             | 08/06/93         | 600 | 0.1% - 90.403%     |
| OPHTHALMIC; SOLUTION                                  |           | 1            |             |                  |     |                    |
| OTIC; OINTMENT  |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION                                     |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                              |           | 31           |             | 07/11/90         | 520 | 4.0% - 25.0%       |
| TOPICAL; LOTION                                       |           | 2            |             | 03/28/73         | 600 | 2.5%               |
| TOPICAL; OINTMENT                                     |           | 46           |             | 12/29/93         | UNK | 0.086725% - 99.98% |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| PETROLATUM                                     | 008009038 |              |             |                  |     |                    |
| TOPICAL; OINTMENT, AUGMENTED                   |           | 1            |             |                  |     |                    |
| TRANSDERMAL; OINTMENT                          |           | 1            |             |                  |     |                    |
| VAGINAL; OINTMENT                              |           | 1            |             |                  |     |                    |
| PETROLATUM, WHITE                              |           |              |             |                  |     |                    |
| NASAL; OINTMENT                                |           | 1            |             |                  |     |                    |
| OPHTHALMIC; OINTMENT                           |           | 15           |             | 10/30/95         | 600 | 49.8% - 85.0%      |
| TOPICAL; CREAM, AUGMENTED                      |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                       |           | 37           |             | 04/01/94         | UNK | 1.0% - 53.9%       |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                    |
| TOPICAL; OINTMENT                              |           | 41           |             | 05/31/95         | 600 | 0.0867% - 95.785%  |
| TOPICAL; OINTMENT, AUGMENTED                   |           | 1            |             |                  |     |                    |
| PHARMA-SWEET 24052                             |           |              |             |                  |     |                    |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                    |
| PHARMACEUTICAL GLAZE                           |           |              |             |                  |     |                    |
| ORAL; CAPSULE                                  |           | 31           |             | 03/30/95         | 600 | 0.945MG - 34.48MG  |
| ORAL; CAPSULE, COATED PELLETS                  |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 43           |             | 02/14/94         | 600 | 0.0126ML - 0.055ML |
| ORAL; TABLET                                   |           | 13           |             | 01/12/89         | 600 | 18.0MG             |
| ORAL; TABLET, COATED                           |           | 10           |             | 09/10/87         | 600 | 0.76MG - 3.4MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 2            |             | 05/15/90         | 600 |                    |
| ORAL; TABLET, FILM COATED                      |           | 4            |             | 06/23/82         | 600 | 0.182MG - 0.74MG   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 5            |             | 06/30/94         | 600 | 4.5MG - 6.8MG      |
| PHARMACOAT 606                                 |           |              |             |                  |     |                    |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                    |
| PHENOL   | 000108952 |              |             |                  |     |                    |
| IM - IV - SC; INJECTION                        |           | 1            |             |                  |     |                    |
| IM - IV; INJECTION                             |           | 26           |             | 12/20/94         | 600 | 0.125% - 2.5%      |
| IM - SC; INJECTION                             |           | 3            |             | 04/14/95         | 600 | 0.068% - 0.5%      |
| IM - SC; INJECTION, SUSTAINED ACTION           |           | 2            |             | 09/12/57         | 510 | 0.5%               |
| INTRA-ARTICULAR; INJECTION                     |           | 3            |             | 01/30/79         | 600 | 0.5%               |
| INTRADERMAL; INJECTION                         |           | 2            |             | 02/08/77         | 510 | 0.25%              |
| INTRALESIONAL; INJECTION                       |           | 3            |             | 01/30/79         | 600 | 0.5%               |
| INTRAMUSCULAR; INJECTION                       |           | 18           |             | 05/31/94         | 600 | 0.25% - 0.5%       |
| INTRASYNOVIAL; INJECTION                       |           | 1            |             |                  |     |                    |
| INTRAVENOUS; INJECTION                         |           | 7            |             | 08/31/94         | 600 | 0.25% - 0.5%       |
| IV(INFUSION); INJECTION                        |           | 5            |             | 05/31/94         | 600 | 0.5%               |
| SOFT TISSUE; INJECTION                         |           | 2            |             | 01/30/79         | 600 | 0.5%               |
| SUBCUTANEOUS; INJECTION                        |           | 9            |             | 07/01/91         | 510 | 0.065% - 0.5%      |
| SUBCUTANEOUS; SOLUTION, INJECTION              |           | 1            |             |                  |     |                    |
| PHENOL, LIQUEFIED                              |           |              |             |                  |     |                    |
| IM - IV; INJECTION                             |           | 2            |             | 01/30/92         | 600 | 0.5%               |
| SUBCUTANEOUS; INJECTION                        |           | 3            |             | 04/25/89         | 510 | 0.065%             |
| SUBCUTANEOUS; SUSPENSION, INJECTION            |           | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                        | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|--|-----------|--------------|-------------|------------------|-----|----------------|
| PHENYLETHYL ALCOHOL                                    | 000060128 | 3            |             | 10/19/94         | UNK | 0.25%          |
| NASAL; SPRAY, METERED                                  |           | 1            |             |                  |     |                |
| OPHTHALMIC; SOLUTION                                   |           | 1            |             |                  |     |                |
| OPHTHALMIC; SUSPENSION                                 |           | 1            |             |                  |     |                |
| OTIC; SOLUTION   |           | 1            |             |                  |     |                |
| PHENYLMERCURIC ACETATE                                 | 000062384 | 3            |             | 12/03/86         | 600 | 0.0008%        |
| OPHTHALMIC; OINTMENT                                   |           | 1            |             |                  |     |                |
| PHENYLMERCURIC NITRATE                                 | 000055685 | 1            |             |                  |     |                |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION          |           | 1            |             |                  |     |                |
| OPHTHALMIC; SOLUTION                                   |           | 1            |             |                  |     |                |
| PHOSPHATE BUFFER                                       |           | 1            |             |                  |     |                |
| ORAL; SOLUTION   |           | 1            |             |                  |     |                |
| PHOSPHOLIPID   |           | 3            |             | 12/30/93         | 510 | 1.2%           |
| IV(INFUSION); INJECTION                                |           | 1            |             |                  |     |                |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION, LYOPHILI |           | 1            |             |                  |     |                |
| PHOSPHORIC ACID  | 007664382 | 1            |             |                  |     |                |
| IM - IV; INJECTION                                     |           | 1            |             |                  |     |                |
| INTRA-ARTICULAR; INJECTION                             |           | 1            |             |                  |     |                |
| INTRALESIONAL; INJECTION                               |           | 1            |             |                  |     |                |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION          |           | 2            |             | 10/17/85         | 510 |                |
| INTRAVENOUS; SOLUTION                                  |           | 1            |             |                  |     |                |
| IV(INFUSION); INJECTION                                |           | 3            |             | 02/26/93         | 150 |                |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION           |           | 5            |             | 08/31/95         | 600 |                |
| ORAL; SOLUTION   |           | 1            |             |                  |     |                |
| SOFT TISSUE; INJECTION                                 |           | 1            |             |                  |     |                |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION           |           | 2            |             | 10/24/89         | 510 |                |
| TOPICAL; EMULSION, CREAM                               |           | 16           |             | 04/30/92         | 600 | 0.002% - 10.0% |
| TOPICAL; LOTION  |           | 4            |             | 03/30/89         | UNK |                |
| TOPICAL; LOTION, AUGMENTED                             |           | 1            |             |                  |     |                |
| TOPICAL; OINTMENT                                      |           | 1            |             |                  |     |                |
| TOPICAL; SOLUTION                                      |           | 1            |             |                  |     |                |
| TOPICAL; SPONGE  |           | 2            |             | 01/07/87         | 520 |                |
| VAGINAL; EMULSION, CREAM                               |           | 6            |             | 06/09/86         | 600 | 0.07% - 0.8%   |
| PINE NEEDLE OIL  |           | 1            |             |                  |     |                |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                |
| PINEAPPLE  |           | 1            |             |                  |     |                |
| ORAL; POWDER, FOR RECONSTITUTION                       |           | 1            |             |                  |     |                |
| PIPERAZINE   | 000110850 | 4            |             | 09/23/93         | 600 |                |
| ORAL; TABLET   |           | 1            |             |                  |     |                |
| PIPERAZINE HEXAHYDRATE                                 | 000142632 | 1            |             |                  |     |                |
| VAGINAL; EMULSION, CREAM                               |           | 1            |             |                  |     |                |
| PLASTIBASE-50W   |           | 3            |             | 06/15/88         | 600 | 99.95%         |
| TOPICAL; OINTMENT                                      |           | 1            |             |                  |     |                |
| PLUSWEET   |           | 1            |             |                  |     |                |
| SUBLINGUAL; TABLET                                     |           | 1            |             |                  |     |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| POLACRILIN                                     | 050602216 |              |             |                  |     |                 |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                 |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                 |
| POLACRILIN POTASSIUM                           | 039393765 |              |             |                  |     |                 |
| ORAL; CAPSULE                                  |           | 9            |             | 08/22/88         | 600 | 1.56MG - 23.0MG |
| ORAL; TABLET                                   |           | 37           |             | 09/23/93         | 600 | 0.45MG - 45.8MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                 |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                 |
| ORAL-21; TABLET                                |           | 9            |             | 12/30/91         | 600 | 1.0MG - 3.0MG   |
| ORAL-28; TABLET                                |           | 8            |             | 12/30/91         | 600 | 1.0MG - 3.0MG   |
| POLISTIREX                                     |           |              |             |                  |     |                 |
| OPHTHALMIC; SUSPENSION                         |           | 1            |             |                  |     |                 |
| POLOXAMER                                      | 106392125 |              |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                           |           | 1            |             |                  |     |                 |
| ORAL; GRANULE                                  |           | 1            |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 09/15/80         | 600 | 0.5% - 0.51852% |
| ORAL; SOLUTION                                 |           | 3            |             | 06/01/94         | 600 | 10.0%           |
| ORAL; SUSPENSION                               |           | 2            |             | 12/18/87         | 120 | 0.02%           |
| ORAL; TABLET                                   |           | 1            |             | 05/02/89         | 520 | 2.68MG          |
| TOPICAL; SOLUTION                              |           | 2            |             | 07/25/89         | 520 | 0.2%            |
| TOPICAL; SPONGE                                |           | 1            |             |                  |     |                 |
| POLOXAMER 188                                  | 106392125 |              |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 1            |             |                  |     |                 |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                 |
| ORAL; GRANULE                                  |           | 1            |             |                  |     |                 |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                 |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                 |
| POLOXAMER 331                                  |           |              |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 3            |             | 02/13/87         | 600 | 0.5286%         |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                 |
| POLOXAMER 407                                  | 009003116 |              |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                           |           | 4            |             | 12/29/95         | 600 | 0.1% - 0.16%    |
| POLYBUTENE                                     |           |              |             |                  |     |                 |
| TRANSDERMAL; FILM, CONTROLLED RELEASE          |           | 1            |             |                  |     |                 |
| POLYDEXTROSE                                   | 068424044 |              |             |                  |     |                 |
| ORAL; TABLET                                   |           | 2            |             | 01/27/94         | 600 |                 |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                 |
| POLYDEXTROSE K                                 |           |              |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 08/31/94         | 600 |                 |
| POLYESTER                                      |           |              |             |                  |     |                 |
| TRANSDERMAL; FILM, CONTROLLED RELEASE          |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| POLYETHYLENE                                   | 009002884 |              |             |                  |     |                  |
| DENTAL; PASTE                                  |           | 2            |             | 10/01/86         | 600 | 4.0%             |
| INTRAUTERINE; INTRAUTERINE DEVICE              |           | 1            |             |                  |     |                  |
| OPHTHALMIC; OINTMENT                           |           | 3            |             | 12/12/80         | UNK |                  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                  |
| TOPICAL; OINTMENT                              |           | 7            |             | 06/15/88         | 600 | 5.0% - 9.0%      |
| TOPICAL; PASTE                                 |           | 1            |             |                  |     |                  |
| TOPICAL; TAPE                                  |           | 1            |             |                  |     |                  |
| TRANSDERMAL; FILM, CONTROLLED RELEASE          |           | 2            |             | 12/22/94         | 510 | 27.0MG - 85.0MG  |
| VAGINAL; SUPPOSITORY                           |           | 1            |             |                  |     |                  |
| POLYETHYLENE GLYCOL                            | 025322683 |              |             |                  |     |                  |
| IM - IV; INJECTION                             |           | 1            |             |                  |     |                  |
| INTRAVENOUS; INJECTION                         |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION                           |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 14           |             | 07/31/92         | 600 | 1.1MG - 10.0MG   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                  |
| ORAL; CONCENTRATE                              |           | 2            |             | 07/20/88         | 600 | 50.0% - 60.0%    |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 202          |             | 10/04/95         | 510 | 0.045MG - 37.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                           |           | 19           |             |                  |     |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 4            |             | 09/17/76         | 110 |                  |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 1            |             | 11/30/95         | 600 | 4.5MG - 4.63MG   |
| ORAL; TABLET, FILM COATED                      |           | 49           |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 15           |             | 12/08/95         | UNK | 0.013MG - 3.17MG |
| ORAL-21; TABLET                                |           | 1            |             | 09/22/94         | 110 | 1.3MG - 3.46MG   |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION                              |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM                       |           | 6            |             | 02/06/89         | 600 |                  |
| TOPICAL; GEL                                   |           | 1            |             |                  |     |                  |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                  |
| TOPICAL; OINTMENT                              |           | 2            |             | 10/10/85         | 600 |                  |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                  |
| VAGINAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                  |
| POLYETHYLENE GLYCOL T-DODECYLTHIOETHER         |           |              |             |                  |     |                  |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                  |
| POLYETHYLENE GLYCOL 1000                       |           |              |             |                  |     |                  |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION                                 |           | 4            |             | 12/05/88         | 600 | 15.0%            |
| RECTAL; SUPPOSITORY                            |           | 3            |             | 10/05/81         | 600 | 1.6255GM         |
| TOPICAL; EMULSION, CREAM                       |           | 6            |             | 11/06/88         | 600 | 3.1% - 5.0%      |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM    | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|------------------------------------|-----------|--------------|-------------|------------------|-----|----------------|
| POLYETHYLENE GLYCOL 1450           |           | 1            |             |                  |     |                |
| ORAL; SUSPENSION                   |           | 1            |             |                  |     |                |
| TOPICAL; OINTMENT                  |           | 1            |             |                  |     |                |
| POLYETHYLENE GLYCOL 1500           |           | 1            |             |                  |     |                |
| TOPICAL; OINTMENT                  |           | 1            |             |                  |     |                |
| POLYETHYLENE GLYCOL 1540           |           | 1            |             |                  |     |                |
| DENTAL; GEL                        |           | 1            |             |                  |     |                |
| DENTAL; PASTE                      |           | 1            |             |                  |     |                |
| ORAL; CAPSULE                      |           | 1            |             |                  |     |                |
| ORAL; SOLUTION                     |           | 1            |             |                  |     |                |
| RECTAL; SUPPOSITORY                |           | 1            |             |                  |     |                |
| TOPICAL; OINTMENT                  |           | 1            |             |                  |     |                |
| TOPICAL; SOLUTION                  |           | 1            |             |                  |     |                |
| POLYETHYLENE GLYCOL 200            |           | 2            |             | 01/27/81         | 120 |                |
| ORAL; CAPSULE                      |           | 2            |             | 06/03/77         | 600 | 39.0%          |
| TOPICAL; OINTMENT                  |           | 1            |             |                  |     |                |
| POLYETHYLENE GLYCOL 20000          |           | 2            |             |                  |     |                |
| ORAL; CAPSULE                      |           | 1            |             |                  |     |                |
| ORAL-28; TABLET                    |           | 2            |             | 11/17/95         | 510 | 0.3MG          |
| POLYETHYLENE GLYCOL 300            | 025322683 | 2            |             |                  |     |                |
| IM - IV; INJECTION                 |           | 2            |             | 07/03/80         | 600 | 50.0%          |
| INTRAVENOUS; INJECTION             |           | 2            |             | 07/17/95         | 600 | 65.0%          |
| IV(INFUSION); INJECTION            |           | 5            |             | 08/30/95         | 600 | 50.0% - 65.0%  |
| OPHTHALMIC; OINTMENT               |           | 1            |             |                  |     |                |
| OPHTHALMIC; SOLUTION               |           | 1            |             |                  |     |                |
| ORAL; TABLET, FILM COATED          |           | 1            |             |                  |     |                |
| TOPICAL; OINTMENT                  |           | 3            |             | 06/15/77         | UNK | 57.0%          |
| TOPICAL; SOLUTION                  |           | 2            |             | 07/22/81         | 600 | 29.7%          |
| POLYETHYLENE GLYCOL 3350           |           | 2            |             |                  |     |                |
| INTRA-ARTICULAR; INJECTION         |           | 1            |             | 09/05/61         | UNK | 3.0%           |
| INTRALESIONAL; INJECTION           |           | 3            |             |                  |     |                |
| INTRAMUSCULAR; INJECTION           |           | 2            |             | 10/29/92         | 510 | 2.03% - 3.0%   |
| INTRASYNOVIAL; INJECTION           |           | 2            |             | 09/05/61         | UNK | 3.0%           |
| NASAL; SPRAY, METERED              |           | 1            |             |                  |     |                |
| ORAL; CAPSULE                      |           | 1            |             |                  |     |                |
| ORAL; SUSPENSION, SUSTAINED ACTION |           | 1            |             |                  |     |                |
| ORAL; TABLET                       |           | 6            |             |                  |     |                |
| ORAL; TABLET, COATED               |           | 1            |             | 10/22/87         | 520 | 0.6MG - 1.0 MG |
| ORAL; TABLET, SUSTAINED ACTION     |           | 4            |             |                  |     |                |
| RECTAL; SUPPOSITORY                |           | 3            |             | 08/01/94         | 110 | 0.6MG - 1.25MG |
| SOFT TISSUE; INJECTION             |           | 3            |             | 08/31/92         | 600 |                |
| TOPICAL; OINTMENT                  |           | 1            |             |                  |     |                |
| VAGINAL; SUPPOSITORY               |           | 6            |             | 12/31/81         | 520 | 22.0% - 39.0%  |
| POLYETHYLENE GLYCOL 3500           |           | 1            |             |                  |     |                |
| ORAL; TABLET, FILM COATED          |           | 2            |             | 10/03/90         | 600 |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| POLYETHYLENE GLYCOL 40 SORBITAN DIISOSTEARATE<br>DENTAL; SOLUTION |           | 3            |             | 12/28/95         | 600 | 0.08% - 2.265%     |
| POLYETHYLENE GLYCOL 400<br>IM - IV; INJECTION                     | 009004960 | 6            |             | 05/27/94         | 600 | 18.0%              |
| INTRAVENOUS; INJECTION  |           | 1            |             |                  |     |                    |
| NASAL; SPRAY, METERED   |           | 1            |             |                  |     |                    |
| ORAL; AEROSOL SPRAY   |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE   |           | 7            |             | 07/30/93         | 600 | 0.25GM             |
| ORAL; CAPSULE, COATED, SOFT GELATIN                               |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SOFT GELATIN                                       |           | 4            |             | 02/19/92         | 600 | 520.41MG - 544.0MG |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                    |
| ORAL; SYRUP   |           | 2            |             | 01/04/85         | 600 |                    |
| ORAL; TABLET  |           | 19           |             | 07/29/94         | 600 | 0.15MG - 1.5MG     |
| ORAL; TABLET, FILM COATED   |           | 2            |             | 10/27/89         | 110 | 1.45GM             |
| ORAL; TABLET, SUSTAINED ACTION                                    |           | 1            |             |                  |     |                    |
| ORAL-28; TABLET   |           | 1            |             |                  |     |                    |
| RECTAL; SUPPOSITORY   |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM  |           | 5            |             | 09/04/92         | UNK | 1.0% - 53.0%       |
| TOPICAL; LOTION   |           | 2            |             | 06/13/88         | UNK | 5.0%               |
| TOPICAL; OINTMENT   |           | 8            |             | 12/31/87         | 520 | 58.9% - 65.0%      |
| TOPICAL; SOLUTION   |           | 5            |             | 04/01/91         | 600 | 8.89% - 49.8875%   |
| VAGINAL; SUPPOSITORY  |           | 2            |             | 01/27/87         | 520 |                    |
| POLYETHYLENE GLYCOL 4000<br>INTRA-ARTICULAR; INJECTION            |           | 5            |             | 03/26/79         | 600 | 2.8% - 3.0%        |
| INTRALESIONAL; INJECTION  |           | 3            |             | 03/26/79         | 600 | 2.8% - 2.96%       |
| INTRAMUSCULAR; INJECTION  |           | 5            |             | 03/26/79         | 600 | 2.8% - 3.0%        |
| INTRASYNOVIAL; INJECTION  |           | 3            |             | 03/26/79         | 600 | 2.8% - 3.0%        |
| ORAL; CAPSULE   |           | 2            |             | 09/20/90         | 600 | 23.0MG - 449.6MG   |
| ORAL; TABLET  |           | 15           |             | 10/06/95         | UNK | 0.2MG - 15.0MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                      |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED   |           | 2            |             | 08/31/94         | UNK |                    |
| ORAL; TABLET, SUSTAINED ACTION, COATED                            |           | 1            |             |                  |     |                    |
| RECTAL; SUPPOSITORY   |           | 2            |             | 10/05/81         | 600 | 875.0MG            |
| SOFT TISSUE; INJECTION  |           | 3            |             | 03/26/79         | 600 | 2.8% - 2.96%       |
| SUBLINGUAL; TABLET  |           | 2            |             | 04/16/81         | 600 | 2.5MG              |
| TOPICAL; EMULSION, CREAM  |           | 2            |             | 01/29/93         | 600 | 25.0%              |
| TOPICAL; OINTMENT   |           | 5            |             | 05/11/81         | 600 | 34.8% - 84.0%      |
| TOPICAL; SOLUTION   |           | 1            |             |                  |     |                    |
| VAGINAL; EMULSION, CREAM  |           | 1            |             |                  |     |                    |
| VAGINAL; SUPPOSITORY  |           | 1            |             |                  |     |                    |
| POLYETHYLENE GLYCOL 600<br>INTRAVENOUS; SOLUTION, INJECTION       | 006790096 | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SOFT GELATIN                                       |           | 1            |             |                  |     |                    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                      |           | 1            |             |                  |     |                    |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                         | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| POLYETHYLENE GLYCOL 6000                                |           |              |             |                  |     |                    |
| ORAL; CAPSULE   |           | 2            |             | 12/10/81         | 600 | 1.372MG - 1.79MG   |
| ORAL; CAPSULE, HARD GELATIN                             |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION                         |           | 3            |             | 01/04/95         | 600 | 5.82MG - 17.46MG   |
| ORAL; TABLET  |           | 15           |             | 06/29/95         | 600 | 0.033MG - 375.0MG  |
| ORAL; TABLET, COATED                                    |           | 2            |             | 09/06/73         | 600 | 5.2MG - 40.0MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED            |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                               |           | 3            |             | 12/12/95         | 120 | 0.89MG - 30.0MG    |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 3            |             | 03/30/95         | 110 | 0.5MG - 4.0MG      |
| RECTAL; SUPPOSITORY                                     |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                                |           | 1            |             |                  |     |                    |
| POLYETHYLENE GLYCOL 8000                                |           |              |             |                  |     |                    |
| OPHTHALMIC; SOLUTION                                    |           | 2            |             | 07/11/94         | UNK | 2.0%               |
| ORAL; CAPSULE   |           | 9            |             | 07/18/85         | 600 | 1.0MG - 4.9MG      |
| ORAL; TABLET  |           | 26           |             | 12/21/93         | 600 | 0.096MG - 100.0MG  |
| ORAL; TABLET, COATED                                    |           | 6            |             | 05/19/92         | 110 | 0.08MG - 0.67MG    |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 4            |             | 06/01/94         | 110 | 0.06MG - 13.3MG    |
| ORAL-21; TABLET   |           | 1            |             |                  |     |                    |
| ORAL-28; TABLET   |           | 1            |             |                  |     |                    |
| RECTAL; SUPPOSITORY                                     |           | 2            |             | 08/31/92         | 600 |                    |
| TOPICAL; EMULSION, CREAM                                |           | 4            |             | 10/17/94         | 600 | 5.0%               |
| TOPICAL; POWDER   |           | 1            |             |                  |     |                    |
| TOPICAL; SOLUTION                                       |           | 1            |             |                  |     |                    |
| VAGINAL; TABLET   |           | 1            |             |                  |     |                    |
| POLYETHYLENE GLYCOL 900                                 |           |              |             |                  |     |                    |
| TOPICAL; OINTMENT                                       |           | 1            |             |                  |     |                    |
| POLYETHYLENE OXIDE                                      | 025322683 |              |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 3            |             | 06/01/94         | 110 | 82.49MG - 277.15MG |
| POLYETHYLENE TEREPHTHALATES                             | 009003514 |              |             |                  |     |                    |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                   |           | 1            |             |                  |     |                    |
| POLYLACTIN  | 026780507 |              |             |                  |     |                    |
| IMPLANTATION; PELLET, IMPLANT                           |           | 2            |             | 12/18/95         | 150 |                    |
| INTRAMUSCULAR; INJECTION                                |           | 2            |             | 01/21/94         | 510 | 6.62%              |
| SUBCUTANEOUS; PELLET, IMPLANT                           |           | 2            |             | 12/18/95         | 150 |                    |
| POLYGLYCERYL-10 TETRALINOLEATE                          |           |              |             |                  |     |                    |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                    |
| POLYISOBUTYLENE   | 009003274 |              |             |                  |     |                    |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                   |           | 6            |             | 10/28/94         | 510 | 6.3MG - 119.0MG    |
| POLYISOBUTYLENE 1,200,000                               |           |              |             |                  |     |                    |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                   |           | 1            |             |                  |     |                    |
| POLYLACTIDE   |           |              |             |                  |     |                    |
| INTRAMUSCULAR; POWDER, FOR INJECTION SUSPENSION, LYOPHI |           | 1            |             |                  |     |                    |
| POLYMERS  |           |              |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION                          |           | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM          | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE |
|--|-----------|--------------|-------------|------------------|-----|---------------|
| POLYOLS                                  |           |              |             |                  |     |               |
| DENTAL; GEL                              |           | 1            |             |                  |     |               |
| DENTAL; PASTE                            |           | 1            |             |                  |     |               |
| POLYOXYETHYLENE - POLYOXYPROPYLENE 1800  |           |              |             |                  |     |               |
| OPHTHALMIC; SOLUTION                     |           | 1            |             |                  |     |               |
| TOPICAL; EMULSION, CREAM                 |           | 1            |             |                  |     |               |
| POLYOXYETHYLENE ALCOHOLS                 | 009007630 |              |             |                  |     |               |
| TOPICAL; EMULSION, CREAM                 |           | 7            |             | 12/22/87         | 600 | 7.5% - 9.14%  |
| TOPICAL; OINTMENT                        |           | 1            |             |                  |     |               |
| POLYOXYETHYLENE FATTY ACID ESTERS        |           |              |             |                  |     |               |
| IM - IV - SC; INJECTION                  |           | 1            |             |                  |     |               |
| IM - SC; INJECTION                       |           | 1            |             |                  |     |               |
| POLYOXYETHYLENE PROPYLENE                |           |              |             |                  |     |               |
| TOPICAL; LOTION                          |           | 1            |             |                  |     |               |
| POLYOXYETHYLENE SORBITAN MONOISOSTEARATE |           |              |             |                  |     |               |
| INTRAMUSCULAR; INJECTION                 |           | 1            |             |                  |     |               |
| POLYOXYL CASTOR OIL                      | 008047163 |              |             |                  |     |               |
| IV(INFUSION); INJECTION                  |           | 1            |             |                  |     |               |
| POLYOXYL DISTEARATE                      | 009005087 |              |             |                  |     |               |
| TOPICAL; OINTMENT                        |           | 1            |             |                  |     |               |
| POLYOXYL GLYCERYL STEARATE               |           |              |             |                  |     |               |
| TOPICAL; EMULSION, CREAM                 |           | 1            |             |                  |     |               |
| POLYOXYL LANOLIN                         |           |              |             |                  |     |               |
| TOPICAL; SOLUTION                        |           | 1            |             |                  |     |               |
| POLYOXYL STEARATE                        |           |              |             |                  |     |               |
| OTIC; SUSPENSION                         |           | 1            |             |                  |     |               |
| RECTAL; SUPPOSITORY                      |           | 1            |             |                  |     |               |
| TOPICAL; EMULSION                        |           | 1            |             |                  |     |               |
| TOPICAL; EMULSION, CREAM                 |           | 8            |             | 07/26/88         | 600 | 1.0% - 20.0%  |
| TOPICAL; LOTION                          |           | 1            |             |                  |     |               |
| POLYOXYL 100 GLYCERYL STEARATE           |           |              |             |                  |     |               |
| TOPICAL; EMULSION, CREAM                 |           | 1            |             |                  |     |               |
| VAGINAL; EMULSION, CREAM                 |           | 1            |             |                  |     |               |
| POLYOXYL 100 STEARATE                    |           |              |             |                  |     |               |
| TOPICAL; EMULSION, CREAM                 |           | 2            |             | 02/16/94         | 600 |               |
| TOPICAL; LOTION                          |           | 1            |             |                  |     |               |
| VAGINAL; EMULSION, CREAM                 |           | 1            |             |                  |     |               |
| POLYOXYL 15 COCAMINE                     | 008051523 |              |             |                  |     |               |
| TOPICAL; SPONGE                          |           | 1            |             |                  |     |               |
| POLYOXYL 150 DISTEARATE                  |           |              |             |                  |     |               |
| TOPICAL; SOLUTION                        |           | 1            |             |                  |     |               |
| POLYOXYL 2 STEARATE                      |           |              |             |                  |     |               |
| TOPICAL; EMULSION, AEROSOL FOAM          |           | 1            |             |                  |     |               |
| TOPICAL; EMULSION, CREAM                 |           | 1            |             |                  |     |               |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY<br>RANGE |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| POLYOXYL 20 STEARATE<br>ORAL; TABLET, SUSTAINED ACTION         |           | 1            |             |                  |     |                  |
| POLYOXYL 35 CASTOR OIL<br>IV(INFUSION); INJECTION              | 061791126 | 1            |             |                  |     |                  |
| IV(INFUSION); SOLUTION, INJECTION                              |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION   |           | 1            |             |                  |     |                  |
| POLYOXYL 40 CASTOR OIL<br>IV(INFUSION); INJECTION              |           | 1            |             |                  |     |                  |
| POLYOXYL 40 HYDROGENATED CASTOR OIL<br>ORAL; SOLUTION          | 061788850 | 1            |             |                  |     |                  |
| POLYOXYL 40 STEARATE<br>DENTAL; SOLUTION                       | 009004993 | 1            |             |                  |     |                  |
| OPHTHALMIC; OINTMENT   |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION   |           | 3            |             | 09/25/85         | 600 | 7.0%             |
| OPHTHALMIC; SUSPENSION   |           | 2            |             | 05/11/88         | 600 | 0.5%             |
| ORAL; CAPSULE  |           | 4            |             | 08/03/87         | 600 | 1.0MG - 2.64MG   |
| ORAL; CONCENTRATE  |           | 1            |             |                  |     |                  |
| ORAL; GRANULE  |           | 1            |             |                  |     |                  |
| ORAL; TABLET   |           | 16           |             |                  |     |                  |
| OTIC; SUSPENSION   |           | 1            |             | 02/21/92         | 520 | 0.8MG - 8.48MG   |
| TOPICAL; EMULSION, AEROSOL FOAM                                |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM                                       |           | 44           |             | 11/20/92         | UNK | 0.45% - 8.8%     |
| TOPICAL; LOTION  |           | 7            |             | 04/24/85         | UNK | 0.502% - 3.5%    |
| TOPICAL; OINTMENT  |           | 2            |             | 07/24/78         | 600 | 3.0%             |
| POLYOXYL 50 STEARATE<br>TOPICAL; OINTMENT                      |           | 1            |             |                  |     |                  |
| POLYOXYL 60 CASTOR OIL<br>IV(INFUSION); INJECTION              |           | 1            |             |                  |     |                  |
| POLYOXYL 75 LANOLIN<br>TOPICAL; SOLUTION                       |           | 1            |             |                  |     |                  |
| POLYOXYL 8 STEARATE<br>TOPICAL; EMULSION, CREAM                | 009004993 | 3            |             | 10/08/85         | 600 | 1.0% - 8.0%      |
| POLYOXYPROPYLENE 15 STEARYL ETHER<br>TOPICAL; OINTMENT         |           | 1            |             |                  |     |                  |
| POLYOXYPROPYLENE 26 OLEATE<br>TOPICAL; EMULSION, CREAM         |           | 2            |             | 06/13/88         | 600 | 1.5% - 4.0%      |
| POLYPROPYLENE<br>TRANSDERMAL; FILM, CONTROLLED RELEASE         | 009003070 | 2            |             | 10/10/84         | 110 | 4.5MG - 13.5MG   |
| POLYPROPYLENE GLYCOL<br>OPHTHALMIC; SOLUTION                   | 009003150 | 1            |             |                  |     |                  |
| ORAL; TABLET   |           | 2            |             | 12/28/88         | 110 | 1.26MG           |
| POLYSACCHARIDE<br>ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 1            |             |                  |     |                  |
| POLYSILOXANE<br>ORAL; CAPSULE                                  | 009014135 | 4            |             | 04/21/87         | 600 |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                           | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| POLYSORBATE 80  | 009005656 |              |             |                  |     |                   |
| IV(INFUSION); INJECTION                                   |           | 6            |             | 08/30/95         | 600 | 0.8% - 8.0%       |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION, LYOPHILIZED |           | 1            |             |                  |     |                   |
| IV(INFUSION); SOLUTION, INJECTION                         |           | 1            |             |                  |     |                   |
| NASAL; SPRAY, METERED                                     |           | 3            |             | 10/19/94         | UNK | 0.005%            |
| OPHTHALMIC; SOLUTION                                      |           | 2            |             | 05/25/71         | 600 | 0.01% - 0.2%      |
| OPHTHALMIC; SUSPENSION                                    |           | 18           |             | 12/30/94         | UNK | 0.002% - 0.1%     |
| ORAL; CAPSULE   |           | 12           |             | 12/20/95         | 520 | 0.14MG - 418.37MG |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                     |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                           |           | 2            |             | 09/11/95         | 110 | 0.071MG           |
| ORAL; CONCENTRATE   |           | 1            |             |                  |     |                   |
| ORAL; DROPS   |           | 1            |             |                  |     |                   |
| ORAL; GRANULE   |           | 4            |             | 06/15/88         | 600 |                   |
| ORAL; POWDER  |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                          |           | 5            |             | 12/20/95         | 520 | 0.028% - 2.625%   |
| ORAL; SOLUTION  |           | 5            |             | 04/22/87         | 600 | 0.1512%           |
| ORAL; SUSPENSION  |           | 22           |             | 06/16/95         | UNK | 0.02% - 0.375%    |
| ORAL; SUSPENSION, SUSTAINED ACTION                        |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 125          |             | 03/31/95         | 600 | 0.04MG - 12.0MG   |
| ORAL; TABLET, COATED                                      |           | 2            |             | 12/20/82         | 600 |                   |
| ORAL; TABLET, FILM COATED                                 |           | 29           |             | 09/14/95         | 110 | 0.0334MG - 14.8MG |
| ORAL; TABLET, SUSTAINED ACTION                            |           | 5            |             | 01/31/94         | 600 | 17.5MG            |
| OTIC; SOLUTION  |           | 1            |             |                  |     |                   |
| OTIC; SUSPENSION  |           | 3            |             | 11/08/83         | 600 | 0.01% - 5.0%      |
| RECTAL; ENEMA   |           | 2            |             | 05/27/94         | 600 |                   |
| RECTAL; POWDER, FOR RECONSTITUTION                        |           | 1            |             |                  |     |                   |
| RECTAL; SOLUTION  |           | 2            |             | 12/17/11         | 100 |                   |
| RECTAL; SUPPOSITORY                                       |           | 8            |             | 02/27/95         | 600 |                   |
| SOFT TISSUE; INJECTION                                    |           | 3            |             | 05/24/82         | 600 | 0.075% - 0.2%     |
| SUBCUTANEOUS; INJECTION                                   |           | 1            |             |                  |     |                   |
| SUBLINGUAL; TABLET  |           | 2            |             | 04/16/81         | 600 | 0.075MG           |
| TOPICAL; EMULSION, CREAM                                  |           | 8            |             | 10/26/94         | 600 | 0.1% - 1.5%       |
| TOPICAL; GEL  |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION   |           | 2            |             | 06/05/78         | 600 | 0.01%             |
| TOPICAL; OINTMENT   |           | 1            |             |                  |     |                   |
| VAGINAL; EMULSION, CREAM                                  |           | 2            |             | 02/21/91         | 520 |                   |
| VAGINAL; SUPPOSITORY                                      |           | 3            |             | 01/27/87         | 520 | 28.0MG            |
| POLYSORBATE 85  | 009005703 |              |             |                  |     |                   |
| IM - IV; INJECTION  |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                                   |           | 1            |             |                  |     |                   |
| POLYVINYL ACETATE   | 009003207 |              |             |                  |     |                   |
| ORAL; TABLET  |           | 2            |             | 09/10/87         | 520 | 7.0MG             |
| ORAL; TABLET, SUSTAINED ACTION                            |           | 3            |             | 01/25/93         | 600 | 20.0MG - 46.0MG   |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                     |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|---|-----------|--------------|-------------|------------------|-----|----------------|
| POLYSORBATE                                   |           |              |             |                  |     |                |
| ORAL; TABLET                                  |           | 4            |             | 11/20/92         | 110 | 0.04MG - 0.9MG |
| ORAL; TABLET, SUSTAINED ACTION                |           | 3            |             | 05/14/85         | UNK |                |
| TOPICAL; EMULSION, CREAM                      |           | 1            |             |                  |     |                |
| POLYSORBATE 20                                | 009005645 |              |             |                  |     |                |
| INTRAVENOUS; INJECTION                        |           | 1            |             |                  |     |                |
| IV(INFUSION); INJECTION                       |           | 2            |             | 08/08/85         | 510 | 0.014%         |
| NASAL; SPRAY, METERED                         |           | 1            |             |                  |     |                |
| OPHTHALMIC; SUSPENSION                        |           | 5            |             | 09/15/95         | 600 | 0.05%          |
| ORAL; CAPSULE                                 |           | 1            |             |                  |     |                |
| ORAL; SUSPENSION                              |           | 2            |             | 07/15/95         | 180 | 0.1%           |
| ORAL; TABLET                                  |           | 2            |             | 12/23/93         | 180 | 0.18MG - 1.8MG |
| ORAL; TABLET, COATED                          |           | 1            |             |                  |     |                |
| ORAL; TABLET, FILM COATED                     |           | 1            |             |                  |     |                |
| SUBCUTANEOUS; SOLUTION, INJECTION             |           | 1            |             |                  |     |                |
| TOPICAL; LOTION                               |           | 6            |             | 08/14/86         | 600 | 0.65% - 7.8%   |
| TOPICAL; SOLUTION                             |           | 2            |             | 04/17/92         | 600 |                |
| POLYSORBATE 40                                | 009005667 |              |             |                  |     |                |
| INTRAMUSCULAR; INJECTION                      |           | 1            |             |                  |     |                |
| ORAL; SOLUTION, ELIXIR                        |           | 2            |             | 04/29/93         | 600 |                |
| ORAL; SUSPENSION                              |           | 2            |             | 09/25/92         | 600 |                |
| ORAL; SYRUP                                   |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                      |           | 7            |             | 04/29/94         | 600 | 2.5% - 2.8%    |
| TOPICAL; LOTION                               |           | 2            |             | 11/30/82         | 600 | 0.5263% - 3.0% |
| TOPICAL; OINTMENT                             |           | 1            |             |                  |     |                |
| POLYSORBATE 60                                | 009005678 |              |             |                  |     |                |
| ORAL; SUSPENSION                              |           | 1            |             |                  |     |                |
| ORAL; TABLET, COATED                          |           | 1            |             |                  |     |                |
| RECTAL; SUPPOSITORY                           |           | 1            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                      |           | 59           |             | 06/13/95         | 600 | 0.2% - 6.1%    |
| TOPICAL; LOTION                               |           | 4            |             | 09/30/92         | UNK | 1.225% - 3.36% |
| TOPICAL; OINTMENT                             |           | 2            |             | 10/09/85         | 600 |                |
| TOPICAL; SHAMPOO                              |           | 4            |             | 09/18/84         | 600 | 9.0% - 15.0%   |
| TOPICAL; SUPPOSITORY                          |           | 1            |             |                  |     |                |
| VAGINAL; EMULSION, CREAM                      |           | 9            |             | 12/21/95         | 520 | 1.0% - 5.0%    |
| VAGINAL; SUPPOSITORY                          |           | 1            |             |                  |     |                |
| POLYSORBATE 80                                | 009005656 |              |             |                  |     |                |
| INTRA-ARTICULAR; INJECTION                    |           | 21           |             | 02/17/84         | 600 | 0.04% - 0.4%   |
| INTRABURSAL; INJECTION                        |           | 5            |             | 02/13/74         | 600 | 0.04% - 0.2%   |
| INTRADERMAL; INJECTION                        |           | 2            |             | 10/16/87         | UNK | 0.04%          |
| INTRALESIONAL; INJECTION                      |           | 7            |             | 10/16/87         | UNK | 0.04% - 0.4%   |
| INTRAMUSCULAR; INJECTION                      |           | 20           |             | 10/29/92         | 510 | 0.04% - 12.0%  |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION |           | 2            |             | 07/21/61         | 120 |                |
| INTRAMUSCULAR; SOLUTION, INJECTION            |           | 1            |             |                  |     |                |
| INTRASYNOVIAL; INJECTION                      |           | 11           |             | 02/17/84         | 600 | 0.04% - 0.4%   |
| INTRAVENOUS; INJECTION                        |           | 4            |             | 07/17/95         | 600 | 8.0%           |
| INTRAVENOUS; SOLUTION, INJECTION              |           | 1            |             |                  |     |                |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| POLYVINYL ACETATE PHTHALATE<br>ORAL; TABLET, SUSTAINED ACTION |           | 1            |             |                  |     |                  |
| POLYVINYL ALCOHOL<br>OPHTHALMIC; SOLUTION                     | 009002895 | 13           |             | 01/04/95         | 600 | 0.25% - 1.4%     |
| OPHTHALMIC; SUSPENSION  |           | 8            |             | 09/29/89         | UNK | 1.4%             |
| ORAL; TABLET  |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                                     |           | 1            |             |                  |     |                  |
| POLYVINYLACETAL<br>ORAL; TABLET                               |           | 1            |             |                  |     |                  |
| POLYVINYLPIRIDINE<br>ORAL; TABLET                             | 000100936 | 1            |             |                  |     |                  |
| POLYVINYLPIRROLIDONE ETHYLCELLULOSE<br>ORAL; TABLET           |           | 1            |             |                  |     |                  |
| POPPY SEED OIL<br>INTRALYMPHATIC; OIL                         | 008002117 | 1            |             |                  |     |                  |
| INTRAUTERINE; OIL   |           | 1            |             |                  |     |                  |
| POTASSIUM ACETATE<br>OPHTHALMIC; POWDER, FOR RECONSTITUTION   | 000127082 | 1            |             |                  |     |                  |
| RECTAL; ENEMA   |           | 1            |             |                  |     |                  |
| POTASSIUM CARBONATE<br>ORAL; CAPSULE                          | 000584087 | 11           |             | 08/26/88         | 600 | 2.552MG - 20.0MG |
| ORAL; SOLUTION  |           | 2            |             | 04/22/87         | 600 | 0.496% - 0.62%   |
| ORAL; TABLET  |           | 15           |             | 05/11/90         | 600 | 3.5MG - 20.0MG   |
| POTASSIUM CHLORIDE<br>CAUDAL BLOCK; INJECTION                 | 007447407 | 1            |             |                  |     |                  |
| EPIDURAL; INJECTION   |           | 3            |             | 12/01/86         | 600 | 0.03%            |
| INTRAOCULAR; SOLUTION   |           | 2            |             | 04/28/95         | 600 | 0.075%           |
| INTRAVENOUS; INJECTION  |           | 1            |             |                  |     |                  |
| INTRAVENOUS; SOLUTION, INJECTION                              |           | 1            |             |                  |     |                  |
| NERVE BLOCK; INJECTION  |           | 6            |             | 12/01/86         | 600 | 0.012% - 0.03%   |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                        |           | 2            |             | 09/22/93         | UNK |                  |
| OPHTHALMIC; SOLUTION  |           | 9            |             | 01/04/95         | 600 | 0.042% - 0.23%   |
| OPHTHALMIC; SUSPENSION  |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE   |           | 13           |             | 08/26/88         | 600 | 0.57MG - 31.0MG  |
| ORAL; TABLET  |           | 12           |             | 05/11/90         | 600 | 7.75MG - 31.0MG  |
| POTASSIUM CITRATE<br>ORAL; SOLUTION                           | 006100056 | 1            |             |                  |     |                  |
| POTASSIUM HYDROXIDE<br>INTRAVENOUS; INJECTION                 | 001310583 | 1            |             |                  |     |                  |
| IV(INFUSION); INJECTION                                       |           | 3            |             | 03/10/88         | 600 |                  |
| ORAL; CAPSULE   |           | 2            |             | 04/21/87         | 600 |                  |
| ORAL; CAPSULE, SOFT GELATIN                                   |           | 1            |             |                  |     |                  |
| ORAL; PASTILLE  |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION  |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---------------------------------------|-----------|--------------|-------------|------------------|-----|-----------------|
| POTASSIUM METABISULFITE               | 004429429 | 1            |             |                  |     |                 |
| IM - IV; INJECTION                    |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                |           | 5            |             | 11/18/85         | 510 |                 |
| IV(INFUSION); INJECTION               |           | 2            |             | 01/22/85         | 600 | 0.12%           |
| NERVE BLOCK; INJECTION                |           | 4            |             | 12/29/95         | 600 | 0.1%            |
| OTIC; SOLUTION                        |           | 1            |             |                  |     |                 |
| OTIC; SUSPENSION                      |           | 1            |             |                  |     |                 |
| RECTAL; ENEMA                         |           | 1            |             |                  |     |                 |
| POTASSIUM PHOSPHATE, DIBASIC          | 007758114 | 1            |             |                  |     |                 |
| INTRAVENOUS; SOLUTION                 |           | 1            |             |                  |     |                 |
| ORAL; SOLUTION                        |           | 2            |             | 03/18/87         | 600 |                 |
| ORAL; SUSPENSION                      |           | 1            |             |                  |     |                 |
| ORAL; SYRUP                           |           | 1            |             |                  |     |                 |
| ORAL; TABLET                          |           | 1            |             |                  |     |                 |
| SUBCUTANEOUS; INJECTION               |           | 1            |             |                  |     |                 |
| POTASSIUM PHOSPHATE, MONOBASIC        | 007778770 | 1            |             |                  |     |                 |
| IM - IV; INJECTION                    |           | 1            |             |                  |     |                 |
| INTRA-ARTICULAR; INJECTION            |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; INJECTION              |           | 2            |             | 11/16/76         | 160 | 0.074%          |
| INTRAVENOUS; INJECTION                |           | 1            |             |                  |     |                 |
| NERVE BLOCK; INJECTION                |           | 6            |             | 03/04/94         | 600 | 0.03402% - 0.2% |
| OPHTHALMIC; SOLUTION                  |           | 1            |             |                  |     |                 |
| OPHTHALMIC; SUSPENSION                |           | 3            |             | 10/31/93         | 600 | 0.095%          |
| ORAL; SYRUP                           |           | 1            |             |                  |     |                 |
| ORAL; TABLET, DISPERSIBLE             |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION        |           | 1            |             |                  |     |                 |
| OTIC; SOLUTION                        |           | 1            |             |                  |     |                 |
| POTASSIUM POLACRILIN                  |           | 2            |             | 05/15/90         | 600 | 24.0MG          |
| ORAL; TABLET                          |           | 5            |             | 09/30/86         | UNK |                 |
| POTASSIUM SORBATE                     | 000590001 | 1            |             |                  |     |                 |
| ORAL; CAPSULE                         |           | 1            |             |                  |     |                 |
| ORAL; CONCENTRATE                     |           | 3            |             | 12/03/86         | 600 |                 |
| ORAL; GRANULE, FOR RECONSTITUTION     |           | 1            |             |                  |     |                 |
| ORAL; SOLUTION                        |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                      |           | 3            |             | 11/10/83         | 600 |                 |
| ORAL; SYRUP                           |           | 3            |             | 11/05/92         | 600 | 0.8MG           |
| ORAL; TABLET                          |           | 3            |             | 02/01/89         | 600 | 0.095% - 0.15%  |
| TOPICAL; EMULSION, CREAM              |           | 10           |             | 06/05/78         | 600 | 0.1%            |
| TOPICAL; LOTION                       |           | 2            |             |                  |     |                 |
| POVIDONE                              | 009003398 | 7            |             | 07/07/83         | 600 | 0.03% - 0.9%    |
| INTRAMUSCULAR; INJECTION              |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION               |           | 1            |             |                  |     |                 |
| OPHTHALMIC; SOLUTION                  |           | 1            |             |                  |     |                 |
| OPHTHALMIC; SUSPENSION                |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE                         |           | 33           |             | 10/18/95         | 600 | 1.8MG - 44.1MG  |
| ORAL; CAPSULE, COATED PELLETS         |           | 3            |             | 06/30/92         | 600 |                 |
| ORAL; CAPSULE, ENTERIC COATED PELLETS |           | 2            |             | 12/22/86         | 600 |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| <b>POVIDONE</b>                                | 009003398 |              |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 26           |             | 02/16/94         | 600 | 0.15MG - 72.0MG |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                 |
| ORAL; GRANULE                                  |           | 2            |             | 05/20/88         | 600 |                 |
| ORAL; GRANULE FOR RECONSTITUTION, CR           |           | 1            |             |                  |     |                 |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                 |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                   |           | 441          |             | 12/28/95         | 600 | 0.012GM         |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 05/14/82         | 520 | 5.0MG           |
| ORAL; TABLET, COATED                           |           | 31           |             | 06/23/95         | 600 | 3.0MG - 49.2MG  |
| ORAL; TABLET, CONTROLLED RELEASE               |           | 1            |             |                  |     |                 |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 6            |             | 08/28/95         | 600 | 1.0MG - 10.66MG |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                      |           | 25           |             | 12/27/95         | 150 | 1.91MG - 40.0MG |
| ORAL; TABLET, REPEAT ACTION                    |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 30           |             | 11/18/94         | UNK | 3.0MG - 60.0MG  |
| ORAL; TABLET, UNCOATED, TROCHE                 |           | 1            |             |                  |     |                 |
| ORAL-21; TABLET                                |           | 18           |             | 12/13/93         | 600 | 0.14MG - 4.0MG  |
| ORAL-28; TABLET                                |           | 24           |             | 11/17/95         | 510 | 0.14MG - 4.5MG  |
| SUBLINGUAL; TABLET                             |           | 2            |             | 04/16/81         | 600 | 6.0MG           |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                 |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                 |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                 |
| VAGINAL; TABLET                                |           | 3            |             | 12/26/91         | 520 | 50.0MG          |
| <b>POVIDONE K25</b>                            | 0         |              |             |                  |     |                 |
| ORAL; TABLET                                   |           | 2            |             | 06/29/95         | 600 | 0.44MG - 52.0MG |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                 |
| <b>POVIDONE K29-32</b>                         |           |              |             |                  |     |                 |
| ORAL; TABLET                                   |           | 6            |             | 07/29/94         | 600 | 0.5MG - 1.0MG   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                 |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                 |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                 |
| <b>POVIDONE K30</b>                            |           |              |             |                  |     |                 |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, HARD GELATIN                    |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                 |
| ORAL; GRANULE, EFFERVESCENT                    |           | 1            |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                   |           | 8            |             | 05/31/94         | 530 | 4.5MG - 18.0MG  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     | .0MG            |
| <b>POVIDONE K90</b>                            |           |              |             |                  |     |                 |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, HARD GELATIN                    |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                   |           | 4            |             | 04/28/95         | 600 | 0.88MG - 18.0MG |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|---|-----------|--------------|-------------|------------------|-----|--------------------|
| POVIDONE K90<br>ORAL; TABLET, FILM COATED     |           | 1            |             |                  |     |                    |
| PROMALGEN TYPE G<br>TOPICAL; LOTION           |           | 1            |             |                  |     |                    |
| PROMULGEN D<br>TOPICAL; LOTION                |           | 1            |             |                  |     |                    |
| VAGINAL; EMULSION, CREAM                      |           | 1            |             |                  |     |                    |
| PROMULGEN G<br>TOPICAL; EMULSION, CREAM       | 009009614 | 1            |             |                  |     |                    |
| TOPICAL; LOTION                               |           | 2            |             | 11/26/85         | 600 | 2.16%              |
| TOPICAL; SHAMPOO                              |           | 1            |             |                  |     |                    |
| PROPANE<br>TOPICAL; AEROSOL SPRAY             | 000074986 | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, AEROSOL FOAM               |           | 1            |             |                  |     |                    |
| PROPENYL GUAETHOL<br>ORAL; CAPSULE            | 000094860 | 1            |             |                  |     |                    |
| PROPYL GALLATE<br>INTRAMUSCULAR; INJECTION    | 000121799 | 1            |             |                  |     |                    |
| ORAL; CONCENTRATE                             |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                      |           | 1            |             |                  |     |                    |
| TOPICAL; GEL                                  |           | 2            |             | 12/30/94         | 600 | 0.01% - 0.05%      |
| TOPICAL; OINTMENT                             |           | 2            |             | 11/13/81         | UNK |                    |
| PROPYLENE CARBONATE<br>TOPICAL; OINTMENT      | 000108327 | 1            |             |                  |     |                    |
| PROPYLENE GLYCOL<br>IM - IV; INJECTION        | 000057556 | 41           |             | 05/27/94         | 600 | 0.04% - 50.0%      |
| IM - IV; SOLUTION, INJECTION                  |           | 1            |             |                  |     |                    |
| INHALATION; SOLUTION                          |           | 1            |             |                  |     |                    |
| INTRAMUSCULAR; INJECTION                      |           | 3            |             | 02/12/86         | 600 | 2.07% - 40.0%      |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION |           | 2            |             | 07/21/61         | 120 |                    |
| INTRAMUSCULAR; SOLUTION, INJECTION            |           | 1            |             |                  |     |                    |
| INTRAVENOUS; INJECTION                        |           | 5            |             | 12/29/89         | 110 | 4.5% - 37.5%       |
| IV(INFUSION); INJECTION                       |           | 16           |             | 09/11/92         | 600 | 0.09% - 40.0%      |
| IV(INFUSION); SOLUTION, INJECTION             |           | 2            |             | 12/31/86         | 110 | 25.0% - 30.0%      |
| NASAL; SPRAY, METERED                         |           | 2            |             | 03/08/95         | UNK |                    |
| OPHTHALMIC; SOLUTION                          |           | 5            |             | 10/11/88         | 600 | 0.12% - 1.0%       |
| OPHTHALMIC; SUSPENSION                        |           | 5            |             | 11/10/93         | UNK | 0.12% - 5.0%       |
| ORAL; CAPLET                                  |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE                                 |           | 16           |             | 03/18/95         | 600 | 52.0MG             |
| ORAL; CAPSULE, SOFT GELATIN                   |           | 3            |             | 07/14/95         | 530 | 0.135MG - 148.31MG |
| ORAL; CAPSULE, SUSTAINED ACTION               |           | 7            |             | 04/25/95         | UNK | 0.15MG - 0.39MG    |
| ORAL; CONCENTRATE                             |           | 17           |             | 11/30/94         | 600 | 0.07% - 90.0%      |
| ORAL; SOLUTION                                |           | 31           |             | 11/17/95         | 530 | 2.0% - 50.0%       |
| ORAL; SOLUTION, ELIXIR                        |           | 9            |             | 10/27/92         | 600 | 25.8917%           |
| ORAL; SUSPENSION                              |           | 17           |             | 12/18/87         | 120 | 0.69% - 8.0%       |
| ORAL; SUSPENSION, SUSTAINED ACTION            |           | 1            |             |                  |     |                    |
| ORAL; SYRUP                                   |           | 44           |             | 01/11/95         | 600 | 5.0% - 7.0%        |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE         |
|--|-----------|--------------|-------------|------------------|-----|-----------------------|
| PROPYLENE GLYCOL                             | 000057556 |              |             |                  |     |                       |
| ORAL; TABLET                                 |           | 93           |             | 08/24/95         | 600 | 0.00006ML - 0.00012ML |
| ORAL; TABLET, COATED                         |           | 4            |             | 12/30/92         | 110 | 0.4MG - 1.0MG         |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 5            |             | 06/19/95         | 520 | 3.46MG - 6.95MG       |
| ORAL; TABLET, ENTERIC COATED PARTICLES       |           | 1            |             |                  |     |                       |
| ORAL; TABLET, FILM COATED                    |           | 25           |             | 05/23/95         | 600 | 0.33MG - 2.1MG        |
| ORAL; TABLET, SUSTAINED ACTION               |           | 7            |             | 04/17/86         | 110 | 0.71MG - 5.3MG        |
| OTIC; SOLUTION                               |           | 11           |             | 12/29/95         | 600 | 2.0% - 94.9%          |
| OTIC; SOLUTION, DROPS                        |           | 1            |             |                  |     |                       |
| OTIC; SUSPENSION                             |           | 4            |             |                  |     |                       |
| RECTAL; EMULSION, AEROSOL FOAM               |           | 1            |             | 09/29/81         | 600 | 2.0% - 10.0%          |
| RECTAL; SUSPENSION                           |           | 2            |             |                  |     |                       |
| TOPICAL; AEROSOL                             |           | 1            |             | 11/11/86         | 600 |                       |
| TOPICAL; CREAM, AUGMENTED                    |           | 1            |             |                  |     |                       |
| TOPICAL; EMULSION, AEROSOL FOAM              |           | 3            |             | 12/19/79         | 600 | 5.376%                |
| TOPICAL; EMULSION, CREAM                     |           | 124          |             | 09/13/95         | UNK | 0.2% - 67.43%         |
| TOPICAL; GEL                                 |           | 9            |             | 12/30/94         | 600 | 3.0% - 98.09%         |
| TOPICAL; LOTION                              |           | 24           |             | 09/30/92         | UNK | 2.0% - 50.0%          |
| TOPICAL; LOTION, AUGMENTED                   |           | 1            |             |                  |     |                       |
| TOPICAL; OINTMENT                            |           | 26           |             | 03/31/95         | 600 | 0.012% - 38.0%        |
| TOPICAL; OINTMENT, AUGMENTED                 |           | 2            |             | 08/31/95         | 600 | 10.0%                 |
| TOPICAL; SHAMPOO                             |           | 1            |             |                  |     |                       |
| TOPICAL; SOLUTION                            |           | 39           |             | 11/30/95         | 600 | 3.0% - 99.99%         |
| TOPICAL; SPONGE                              |           | 2            |             | 02/28/91         | 600 |                       |
| TOPICAL; SUSPENSION, SHAMPOO                 |           | 1            |             |                  |     |                       |
| TOPICAL; SWAB                                |           | 3            |             | 07/30/95         | 600 | 23.0%                 |
| VAGINAL; EMULSION, CREAM                     |           | 12           |             | 12/21/95         | 520 | 3.0% - 14.0%          |
| VAGINAL; GEL                                 |           | 1            |             |                  |     |                       |
| VAGINAL; SUPPOSITORY                         |           | 1            |             |                  |     |                       |
| PROPYLENE GLYCOL ALGINATE                    | 009005372 |              |             |                  |     |                       |
| ORAL; GRANULE, FOR RECONSTITUTION            |           | 1            |             |                  |     |                       |
| ORAL; POWDER                                 |           | 2            |             | 12/05/88         | 510 | 0.002%                |
| PROPYLENE GLYCOL DIACETATE                   | 000623847 |              |             |                  |     |                       |
| OTIC; SOLUTION                               |           | 7            |             | 10/31/94         | 600 | 3.0%                  |
| PROPYLENE GLYCOL MONOLAURATE                 | 001322878 |              |             |                  |     |                       |
| TOPICAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                       |
| PROPYLENE GLYCOL MONOSTEARATE                | 001323393 |              |             |                  |     |                       |
| TOPICAL; EMULSION, CREAM                     |           | 25           |             | 05/31/91         | 600 | 0.3% - 8.0%           |
| TOPICAL; LOTION                              |           | 1            |             |                  |     |                       |
| TOPICAL; OINTMENT                            |           | 4            |             | 04/30/87         | UNK | 2.0%                  |
| TOPICAL; OINTMENT, AUGMENTED                 |           | 2            |             | 08/31/95         | 600 | 2.0%                  |
| VAGINAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                       |
| PROPYLPARABEN                                | 000094133 |              |             |                  |     |                       |
| IM - IV - SC; INJECTION                      |           | 25           |             | 04/11/89         | 600 | 0.02% - 0.2%          |
| IM - IV; INJECTION                           |           | 33           |             | 11/27/91         | 600 | 0.01% - 0.2%          |
| IM - SC; INJECTION                           |           | 1            |             |                  |     |                       |
| INHALATION; SOLUTION                         |           | 5            |             | 06/30/81         | 600 | 0.007% - 0.0150066%   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| PROPYLPARABEN                                  | 000094133 | 3            |             | 06/19/80         | 600 | 0.02%              |
| INTRA-ARTICULAR; INJECTION                     |           | 1            |             |                  |     |                    |
| INTRABURSAL; INJECTION                         |           | 3            |             | 06/19/80         | 600 | 0.02%              |
| INTRALESIONAL; INJECTION                       |           | 27           |             | 02/25/93         | 600 | 0.01% - 0.02%      |
| INTRAMUSCULAR; INJECTION                       |           | 2            |             | 03/01/77         | UNK | 0.02%              |
| INTRASYNOVIAL; INJECTION                       |           | 16           |             | 12/20/91         | UNK | 0.005% - 0.03%     |
| INTRAVENOUS; INJECTION                         |           | 2            |             | 12/05/85         | 180 | 0.015% - 0.02%     |
| IV - SC; INJECTION                             |           | 19           |             | 03/25/94         | 160 | 0.0005% - 0.056%   |
| IV(INFUSION); INJECTION                        |           | 2            |             | 05/18/70         | 510 | 0.017%             |
| NASAL; SOLUTION                                |           | 2            |             | 03/06/72         | 600 | 0.005% - 0.015%    |
| NERVE BLOCK; INJECTION                         |           | 8            |             | 08/31/95         | 600 | 0.01%              |
| OPHTHALMIC; OINTMENT                           |           | 9            |             | 10/18/88         | 600 | 0.01% - 0.015%     |
| OPHTHALMIC; SOLUTION                           |           | 2            |             | 12/28/82         | 600 | 0.01%              |
| OPHTHALMIC; SUSPENSION                         |           | 79           |             | 12/20/95         | 520 | 0.0246MG - 0.188MG |
| ORAL; CAPSULE                                  |           | 2            |             | 01/29/93         | 600 |                    |
| ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GEL |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, COATED, SOFT GELATIN            |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, HARD GELATIN                    |           | 4            |             | 11/22/95         | 150 | 0.05MG - 0.081MG   |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 8            |             | 04/25/95         | UNK |                    |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 23           |             | 09/28/93         | 600 | 0.004% - 0.03%     |
| ORAL; CONCENTRATE                              |           | 5            |             | 12/31/91         | 520 | 0.01% - 0.08%      |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 42           |             | 11/17/95         | 530 | 0.01% - 20.0%      |
| ORAL; SOLUTION                                 |           | 10           |             | 10/27/92         | 600 | 0.02%              |
| ORAL; SOLUTION, ELIXIR                         |           | 41           |             | 09/15/95         | 180 | 0.01% - 0.05%      |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                    |
| ORAL; SUSPENSION, SUSTAINED ACTION             |           | 39           |             | 07/17/95         | 600 | 0.0085% - 0.02%    |
| ORAL; SYRUP                                    |           | 19           |             | 03/30/94         | 600 | 0.0045MG - 0.14MG  |
| ORAL; TABLET                                   |           | 11           |             | 04/08/81         | 600 | 0.002MG            |
| ORAL; TABLET, COATED                           |           | 2            |             | 12/28/87         | 520 | 0.02MG - 0.04MG    |
| ORAL; TABLET, FILM COATED                      |           | 3            |             | 05/22/87         | UNK | 0.12MG             |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                    |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                    |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                    |
| OTIC; SUSPENSION                               |           | 1            |             |                  |     |                    |
| RECTAL; EMULSION, AEROSOL FOAM                 |           | 1            |             |                  |     |                    |
| RECTAL; SOLUTION                               |           | 1            |             |                  |     |                    |
| RECTAL; SUSPENSION                             |           | 2            |             | 11/17/86         | 600 |                    |
| SOFT TISSUE; INJECTION                         |           | 2            |             | 06/19/80         | 600 | 0.02%              |
| SUBCUTANEOUS; INJECTION                        |           | 2            |             | 12/19/91         | UNK | 0.015%             |
| TOPICAL; EMULSION, AEROSOL FOAM                |           | 2            |             | 12/19/79         | 600 | 0.011%             |
| TOPICAL; EMULSION, CREAM                       |           | 50           |             | 10/31/94         | 600 | 0.001% - 0.15%     |
| TOPICAL; GEL                                   |           | 1            |             |                  |     |                    |
| TOPICAL; GEL, JELLY                            |           | 2            |             | 04/29/93         | 600 | 0.003%             |
| TOPICAL; LOTION                                |           | 12           |             | 12/07/92         | UNK | 0.02% - 0.2%       |
| TOPICAL; OINTMENT                              |           | 10           |             | 09/30/94         | 600 | 0.01% - 0.2%       |
| TOPICAL; SHAMPOO                               |           | 1            |             |                  |     |                    |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                     | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---|-----------|--------------|-------------|------------------|-----|-----------------|
| PROPYLPARABEN<br>URETERAL; SOLUTION                 | 000094133 | 1            |             |                  |     |                 |
| VAGINAL; EMULSION, CREAM                            |           | 11           |             | 12/21/95         | 520 | 0.02% - 0.1%    |
| VAGINAL; GEL  |           | 1            |             |                  |     |                 |
| VAGINAL; SUPPOSITORY                                |           | 1            |             |                  |     |                 |
| PROPYLPARABEN SODIUM<br>ORAL; CAPSULE, SOFT GELATIN | 035285699 | 2            |             | 12/30/86         | 150 | 0.12MG - 0.28MG |
| ORAL; POWDER, FOR RECONSTITUTION                    |           | 1            |             |                  |     |                 |
| PROSWEET<br>ORAL; SOLUTION                          |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                                    |           | 1            |             |                  |     |                 |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,      |           | 1            |             |                  |     |                 |
| PROSWEET 604<br>ORAL; SYRUP                         |           | 1            |             |                  |     |                 |
| PROTAMINE SULFATE<br>IM - SC; INJECTION             | 009009658 | 1            |             |                  |     |                 |
| INTRADERMAL; INJECTION                              |           | 2            |             | 02/08/77         | 510 | 0.043% - 0.12%  |
| SUBCUTANEOUS; INJECTION                             |           | 4            |             | 10/28/82         | 510 | 0.035% - 0.036% |
| SUBCUTANEOUS; SUSPENSION, INJECTION                 |           | 1            |             |                  |     |                 |
| PROTEIN HYDROLYSATE<br>TOPICAL; LOTION              | 009015547 | 1            |             |                  |     |                 |
| RA-2397<br>TRANSDERMAL; FILM, CONTROLLED RELEASE    |           | 1            |             |                  |     |                 |
| RA-3011<br>TRANSDERMAL; FILM, CONTROLLED RELEASE    |           | 1            |             |                  |     |                 |
| ROSIN<br>ORAL; CAPSULE                              | 008050097 | 1            |             |                  |     |                 |
| ORAL; TABLET  |           | 1            |             |                  |     |                 |
| ORAL; TABLET, REPEAT ACTION                         |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION                      |           | 1            |             |                  |     |                 |
| SACCHARIN<br>INHALATION; AEROSOL, METERED           | 000081072 | 1            |             |                  |     |                 |
| ORAL; AEROSOL SPRAY                                 |           | 1            |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION                    |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                                    |           | 3            |             | 01/05/78         | 520 |                 |
| ORAL; SYRUP   |           | 2            |             | 01/19/83         | UNK | 0.02%           |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,      |           | 1            |             |                  |     |                 |
| SUBLINGUAL; TABLET                                  |           | 1            |             |                  |     |                 |
| TOPICAL; OINTMENT                                   |           | 4            |             | 06/03/77         | 600 | 0.4% - 0.5%     |
| TOPICAL; SOLUTION                                   |           | 1            |             |                  |     |                 |
| SACCHARIN CALCIUM<br>ORAL; SOLUTION                 | 006381915 | 1            |             |                  |     |                 |
| ORAL; SYRUP   |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| SACCHARIN SODIUM                               | 006155573 |              |             |                  |     |                   |
| BUCCAL/SUBLINGUAL; TABLET                      |           | 1            |             |                  |     |                   |
| DENTAL; GEL                                    |           | 1            |             |                  |     |                   |
| DENTAL; PASTE                                  |           | 1            |             |                  |     |                   |
| DENTAL; SOLUTION                               |           | 4            |             | 12/28/95         | 600 | 0.01% - 0.15%     |
| IM - IV; INJECTION                             |           | 3            |             | 08/29/89         | 600 | 0.09%             |
| INHALATION; AEROSOL, METERED                   |           | 1            |             |                  |     |                   |
| INHALATION; SOLUTION                           |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                       |           | 3            |             | 12/05/88         | 600 | 0.09%             |
| INTRAVENOUS; INJECTION                         |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                        |           | 3            |             | 08/29/89         | 600 | 0.09%             |
| ORAL; CAPSULE                                  |           | 2            |             | 04/30/92         | 600 |                   |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 2            |             | 02/19/92         | 600 | 0.51MG            |
| ORAL; CONCENTRATE                              |           | 4            |             | 05/15/87         | 600 | 0.1% - 1.4%       |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 17           |             | 11/14/91         | 180 |                   |
| ORAL; SOLUTION                                 |           | 30           |             | 07/10/95         | 600 | 0.075% - 0.15%    |
| ORAL; SOLUTION, ELIXIR                         |           | 14           |             | 10/27/92         | 600 | 0.0997% - 0.1057% |
| ORAL; SUSPENSION                               |           | 20           |             | 02/08/95         | 530 | 0.01% - 0.7%      |
| ORAL; SYRUP                                    |           | 52           |             | 06/30/94         | 600 | 0.01% - 0.25%     |
| ORAL; TABLET                                   |           | 5            |             | 09/09/76         | 520 | 19.6MCG           |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 5            |             | 01/04/95         | 600 | 0.5MG - 5.0MG     |
| RECTAL; SOLUTION                               |           | 2            |             | 09/02/81         | 600 | 0.1%              |
| RECTAL; SUSPENSION                             |           | 2            |             | 11/17/86         | 600 |                   |
| SUBLINGUAL; TABLET                             |           | 2            |             | 06/08/84         | 600 | 0.2MG - 1.0MG     |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                   |
| SACCHARIN SODIUM ANHYDROUS                     | 000128449 |              |             |                  |     |                   |
| IM - IV; INJECTION                             |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                       |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                        |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION                                 |           | 2            |             | 06/11/85         | UNK |                   |
| ORAL; SUSPENSION                               |           | 2            |             | 01/05/78         | 520 |                   |
| ORAL; SYRUP                                    |           | 2            |             | 03/22/85         | 600 |                   |
| RECTAL; SOLUTION                               |           | 1            |             |                  |     |                   |
| SATILOLINE H                                   |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                   |
| SEA SPEN                                       |           |              |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                   |
| SESAME OIL                                     | 008008740 |              |             |                  |     |                   |
| IM - SC; INJECTION                             |           | 1            |             |                  |     |                   |
| IM - SC; INJECTION, SUSTAINED ACTION           |           | 2            |             | 07/14/87         | 600 |                   |
| INTRAMUSCULAR; INJECTION                       |           | 19           |             | 06/12/86         | 510 |                   |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| SHELLAC  | 009000593 |              |             |                  |     |                    |
| ORAL; CAPSULE                                  |           | 9            |             | 08/29/95         | 600 | 0.24MG             |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 14           |             | 02/08/95         | UNK | 4.98MG - 60.0MG    |
| ORAL; TABLET                                   |           | 26           |             | 05/31/94         | 530 | 0.001ML - 0.0019ML |
| ORAL; TABLET, COATED                           |           | 13           |             | 09/10/87         | 600 | 1.0MG - 5.0MG      |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                      |           | 6            |             | 11/18/85         | 600 | 1.5MG              |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 4            |             | 01/22/87         | 600 |                    |
| SHELLAC P.V.P. SOLUTION NO. 4                  |           |              |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 4            |             | 04/11/89         | 600 |                    |
| ORAL-28; TABLET                                |           | 2            |             | 11/17/95         | 510 | 5.62MG             |
| SILASTIC BRAND MEDICAL GRADE TUBING            |           |              |             |                  |     |                    |
| IMPLANTATION; PELLET, IMPLANT                  |           | 1            |             |                  |     |                    |
| SILASTIC MEDICAL ADHESIVE, SILICONE TYPE A     |           |              |             |                  |     |                    |
| IMPLANTATION; PELLET, IMPLANT                  |           | 1            |             |                  |     |                    |
| SILICA GEL                                     | 007699414 |              |             |                  |     |                    |
| DENTAL; GEL                                    |           | 1            |             |                  |     |                    |
| DENTAL; PASTE                                  |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE                                  |           | 18           |             | 12/23/92         | 530 | 0.2MG - 5.25MG     |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 1            |             |                  |     |                    |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                    |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 5            |             | 08/06/84         | 520 | 0.1876% - 2.0%     |
| ORAL; TABLET                                   |           | 58           |             | 10/31/91         | 520 | 0.0076M            |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                    |
| ORAL; TABLET, COATED                           |           | 4            |             | 01/22/82         | 600 | 0.3MG - 3.2MG      |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 5            |             | 12/23/92         | UNK | 0.12MG - 40.0MG    |
| SUBLINGUAL; TABLET                             |           | 1            |             |                  |     |                    |
| SILICA, DIATOMACEOUS                           | 007631869 |              |             |                  |     |                    |
| ORAL; CAPSULE                                  |           | 2            |             | 01/15/73         | 600 | 1.0MG - 3.4MG      |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                    |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                    |
| ORAL; SYRUP                                    |           | 2            |             | 07/17/80         | 600 |                    |
| ORAL; TABLET                                   |           | 5            |             | 12/22/76         | 600 | 0.454MG - 5.0MG    |
| SILICON  | 007440213 |              |             |                  |     |                    |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                    |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                    |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 1            |             |                  |     |                    |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                    |
| TOPICAL; LOTION                                |           | 2            |             | 06/05/78         | 600 |                    |
| SILICON DIOXIDE                                | 007631869 |              |             |                  |     |                    |
| ENDOCERVICAL; GEL                              |           | 1            |             |                  |     |                    |
| ORAL; CAPLET                                   |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE                                  |           | 198          |             | 12/29/95         | 600 | 0.08MG - 11.2MG    |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 2            |             | 05/10/95         | 180 |                    |

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| INGREDIENT<br>ROUTE/DOSAGE FORM                       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| SILICON DIOXIDE                                       | 007631869 |              |             |                  |     |                  |
| ORAL; CAPSULE, HARD GELATIN                           |           | 3            |             | 07/30/92         | UNK | 1.5MG            |
| ORAL; CAPSULE, SUSTAINED ACTION                       |           | 17           |             | 04/25/95         | UNK | 0.05MG - 2.258MG |
| ORAL; GRANULE   |           | 1            |             |                  |     |                  |
| ORAL; GRANULE FOR RECONSTITUTION, CR                  |           | 1            |             |                  |     |                  |
| ORAL; GRANULE, ENTERIC COATED                         |           | 1            |             |                  |     |                  |
| ORAL; GRANULE, FOR RECONSTITUTION                     |           | 1            |             |                  |     |                  |
| ORAL; POWDER  |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                      |           | 25           |             | 12/20/95         | 520 |                  |
| ORAL; SUSPENSION                                      |           | 4            |             | 12/16/93         | 180 |                  |
| ORAL; TABLET  |           | 841          |             | 12/22/95         | 600 |                  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,        |           | 7            |             | 07/29/92         | 600 | 2.0MG - 37.5MG   |
| ORAL; TABLET, COATED                                  |           | 13           |             | 11/19/82         | 600 | 0.18MG - 4.8MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED          |           | 7            |             | 06/29/95         | 600 | 0.5MG - 4.28MG   |
| ORAL; TABLET, DISPERSIBLE                             |           | 2            |             | 04/29/93         | 600 |                  |
| ORAL; TABLET, ENTERIC COATED PARTICLES                |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                             |           | 64           |             | 12/12/95         | 120 | 0.5MG - 25.8MG   |
| ORAL; TABLET, SUSTAINED ACTION                        |           | 23           |             | 04/28/95         | 600 | 0.28MG - 45.0MG  |
| ORAL-21; TABLET                                       |           | 2            |             | 12/14/92         | 510 |                  |
| ORAL-28; TABLET                                       |           | 3            |             | 12/14/92         | 510 | 0.65MG           |
| RECTAL; SUPPOSITORY                                   |           | 2            |             | 09/02/77         | UNK |                  |
| SUBLINGUAL; TABLET                                    |           | 6            |             | 09/18/86         | 600 | 0.047MG - 1.0MG  |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                 |           | 1            |             |                  |     |                  |
| VAGINAL; TABLET                                       |           | 1            |             |                  |     |                  |
| VAGINAL; TAMPON                                       |           | 1            |             |                  |     |                  |
| SILICONE  |           |              |             |                  |     |                  |
| INTRAUTERINE; SUPPOSITORY, INSERT, CONTROLLED RELEASE |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE   |           | 15           |             | 12/23/92         | 120 | 0.268MG - 10.0MG |
| ORAL; CAPSULE, HARD GELATIN                           |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                      |           | 3            |             | 04/20/88         | 600 |                  |
| ORAL; SUSPENSION                                      |           | 1            |             |                  |     |                  |
| ORAL; TABLET  |           | 1            |             |                  |     |                  |
| ORAL; TABLET, SUSTAINED ACTION                        |           | 1            |             |                  |     |                  |
| TOPICAL; SUSPENSION, SHAMPOO                          |           | 1            |             |                  |     |                  |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                 |           | 1            |             |                  |     |                  |
| SILICONE EMULSION                                     |           |              |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                      |           | 2            |             | 12/31/91         | 520 | 0.04% - 1.24%    |
| TOPICAL; LOTION                                       |           | 1            |             |                  |     |                  |
| SILICONE/POLYESTER FILM STRIP                         |           |              |             |                  |     |                  |
| TRANSDERMAL; FILM, CONTROLLED RELEASE                 |           | 1            |             |                  |     |                  |
| SIMETHICONE   | 008050815 |              |             |                  |     |                  |
| IM - IV; POWDER, FOR INJECTION SOLUTION               |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE   |           | 6            |             | 03/30/95         | 600 | 0.024MG          |
| ORAL; CAPSULE, SUSTAINED ACTION                       |           | 1            |             |                  |     |                  |
| ORAL; GRANULE   |           | 3            |             | 06/15/88         | 600 |                  |
| ORAL; GRANULE, EFFERVESCENT                           |           | 1            |             |                  |     |                  |
| ORAL; PASTILLE  |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| SIMETHICONE                                  | 008050815 | 5            |             | 12/20/95         | 520 | 0.08% - 0.666%    |
| ORAL; POWDER, FOR RECONSTITUTION             |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION                               |           | 3            |             | 12/16/93         | 180 | 0.0033%           |
| ORAL; SUSPENSION                             |           | 11           |             | 06/19/95         | 180 | 0.0004MG - 1.5MG  |
| ORAL; TABLET                                 |           | 1            |             |                  |     |                   |
| ORAL; TABLET, COATED                         |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 5            |             | 07/02/87         | 600 | 0.64MG - 8.96MG   |
| RECTAL; SOLUTION                             |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                     |           | 14           |             | 10/08/85         | 600 | 0.002% - 1.0%     |
| TOPICAL; LOTION                              |           | 5            |             | 08/14/86         | 600 | 0.05% - 0.5%      |
| TOPICAL; OINTMENT                            |           | 1            |             |                  |     |                   |
| SIMETHICONE EMULSION                         |           | 4            |             | 01/04/95         | 600 | 0.03MG - 0.165MG  |
| ORAL; CAPSULE, SUSTAINED ACTION              |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION             |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                             |           | 3            |             | 07/29/93         | 120 |                   |
| ORAL; TABLET                                 |           | 4            |             | 11/23/87         | 600 | 0.154MG - 0.318MG |
| ORAL; TABLET, COATED                         |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                    |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 2            |             | 04/01/82         | 600 |                   |
| TOPICAL; EMULSION, CREAM                     |           | 3            |             | 12/22/87         | 600 |                   |
| TOPICAL; OINTMENT                            |           | 1            |             |                  |     |                   |
| SIMETHICONE MDX4-4036                        |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 1            |             |                  |     |                   |
| SOAP   |           | 2            |             | 11/14/94         | UNK | 0.4MG             |
| ORAL; TABLET, SUSTAINED ACTION               |           | 2            |             |                  |     |                   |
| SOAP, POTASSIUM                              |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, AEROSOL FOAM              |           | 1            |             |                  |     |                   |
| SOAP, EIDERDOWN                              |           | 2            |             | 03/31/81         | UNK | 0.39MG            |
| ORAL; TABLET, REPEAT ACTION                  |           | 3            |             | 05/14/84         | UNK |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 3            |             |                  |     |                   |
| SODIUM ACETATE                               | 006131904 | 1            |             |                  |     |                   |
| IM - IV - SC; INJECTION                      |           | 9            |             | 05/02/88         | 600 | 0.306% - 0.68%    |
| IM - IV; INJECTION                           |           | 6            |             | 04/14/95         | 600 | 0.04% - 0.2%      |
| IM - SC; INJECTION                           |           | 1            |             |                  |     |                   |
| INTERSTITIAL; INJECTION                      |           | 3            |             | 05/07/78         | 600 |                   |
| INTRA-ARTICULAR; INJECTION                   |           | 1            |             |                  |     |                   |
| INTRACAVITARY; INJECTION                     |           | 1            |             |                  |     |                   |
| INTRADERMAL; INJECTION                       |           | 11           |             | 05/02/88         | 600 | 0.02% - 0.471%    |
| INTRAMUSCULAR; INJECTION                     |           | 2            |             | 04/28/95         | 600 | 0.39%             |
| INTRACULAR; SOLUTION                         |           | 1            |             |                  |     |                   |
| INTRAPERITONEAL; INJECTION                   |           | 1            |             |                  |     |                   |
| INTRAPLEURAL; INJECTION                      |           | 3            |             | 05/07/78         | 600 |                   |
| INTRASYNOVIAL; INJECTION                     |           | 21           |             | 03/17/94         | UNK | 0.00006% - 0.2%   |
| INTRAVENOUS; INJECTION                       |           | 2            |             | 09/30/74         | 160 | 0.16%             |
| INTRAVENOUS; SOLUTION                        |           | 7            |             | 03/25/94         | 160 | 0.013% - 0.15%    |
| IV(INFUSION); INJECTION                      |           | 7            |             |                  |     |                   |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM        | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| SODIUM ACETATE                         | 006131904 | 2            |             | 12/28/95         | 110 | 0.0189% - 1.7%      |
| IV(INFUSION); SOLUTION, INJECTION      |           | 1            |             |                  |     |                     |
| NASAL; SOLUTION                        |           | 1            |             |                  |     |                     |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION |           | 4            |             | 06/17/91         | UNK | 0.07% - 0.272%      |
| OPHTHALMIC; SOLUTION                   |           | 1            |             |                  |     |                     |
| OPHTHALMIC; SUSPENSION                 |           | 2            |             | 12/16/85         | 600 | 0.125%              |
| ORAL; CONCENTRATE                      |           | 2            |             | 09/30/74         | 160 | 0.16%               |
| ORAL; SOLUTION                         |           | 7            |             | 10/31/94         | 600 | 0.015%              |
| OTIC; SOLUTION                         |           | 1            |             |                  |     |                     |
| OTIC; SOLUTION, DROPS                  |           | 2            |             | 12/14/66         | 520 | 0.042% - 1.905%     |
| OTIC; SUSPENSION                       |           | 6            |             | 06/25/91         | 510 | 0.14% - 0.2%        |
| SUBCUTANEOUS; INJECTION                |           |              |             |                  |     |                     |
| SODIUM ACETATE, ANHYDROUS              | 000127093 | 1            |             |                  |     |                     |
| IM - IV; INJECTION                     |           | 1            |             |                  |     |                     |
| IM - SC; INJECTION                     |           | 2            |             | 11/26/82         | 600 | 0.471%              |
| INTRAMUSCULAR; INJECTION               |           | 1            |             |                  |     |                     |
| INTRAVENOUS; SOLUTION                  |           | 1            |             |                  |     |                     |
| IV(INFUSION); INJECTION                |           | 1            |             |                  |     |                     |
| ORAL; SOLUTION                         |           | 3            |             | 09/30/85         | 510 | 0.16%               |
| SUBCUTANEOUS; INJECTION                |           | 1            |             |                  |     |                     |
| TOPICAL; EMULSION, CREAM               |           |              |             |                  |     |                     |
| SODIUM ACID PYROPHOSPHATE              | 007758169 | 1            |             |                  |     |                     |
| TOPICAL; OINTMENT                      |           |              |             |                  |     |                     |
| SODIUM ALGINATE                        | 009005383 | 3            |             | 01/26/84         | 600 | 0.14% - 0.7%        |
| ORAL; SUSPENSION                       |           | 3            |             | 05/01/84         | 510 | 20.0MG              |
| ORAL; TABLET                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, FILM COATED              |           | 2            |             | 07/31/92         | 600 | 320.0MG             |
| ORAL; TABLET, SUSTAINED ACTION         |           |              |             |                  |     |                     |
| SODIUM ALKYL SULFATE                   | 008036542 | 1            |             |                  |     |                     |
| TOPICAL; SUSPENSION, SHAMPOO           |           |              |             |                  |     |                     |
| SODIUM AMINOBENZOATE                   | 000555066 | 3            |             | 02/18/75         | 600 | 0.0011MG - 0.0017MG |
| ORAL; CAPSULE                          |           | 1            |             |                  |     |                     |
| ORAL; TABLET                           |           |              |             |                  |     |                     |
| SODIUM ASCORBATE                       | 000134032 | 1            |             |                  |     |                     |
| INTRAVENOUS; INJECTION                 |           |              |             |                  |     |                     |
| SODIUM BENZOATE                        | 000532321 | 1            |             |                  |     |                     |
| DENTAL; GEL                            |           | 1            |             |                  |     |                     |
| DENTAL; PASTE                          |           | 15           |             | 01/29/93         | 600 | 4.775% - 5.0%       |
| IM - IV; INJECTION                     |           | 1            |             |                  |     |                     |
| INTRAMUSCULAR; INJECTION               |           | 1            |             |                  |     |                     |
| IV(INFUSION); INJECTION                |           | 13           |             | 08/19/91         | 600 | 0.3MG               |
| ORAL; CAPSULE                          |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, HARD GELATIN            |           | 11           |             | 01/30/92         | 600 | 0.05% - 0.2%        |
| ORAL; CONCENTRATE                      |           | 1            |             |                  |     |                     |
| ORAL; DROPS                            |           | 1            |             |                  |     |                     |
| ORAL; GRANULE, FOR RECONSTITUTION      |           | 1            |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION       |           | 28           |             | 12/20/95         | 520 | 0.046% - 0.8%       |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                 | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| <b>SODIUM BENZOATE</b>                          | 000532321 |              |             |                  |     |                  |
| ORAL; SOLUTION                                  |           | 5            |             | 06/30/93         | 600 | 0.1%             |
| ORAL; SOLUTION, ELIXIR                          |           | 5            |             | 04/29/93         | 600 | 0.1% - 0.1506%   |
| ORAL; SUSPENSION                                |           | 14           |             | 06/16/95         | UNK | 0.1%             |
| ORAL; SYRUP                                     |           | 56           |             | 10/28/94         | 600 | 0.1% - 0.5%      |
| ORAL; TABLET                                    |           | 51           |             | 12/29/95         | 600 | 0.1MG - 0.75MG   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,  |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                            |           | 14           |             | 02/25/92         | 600 | 0.012MG - 9.0MG  |
| ORAL; TABLET, FILM COATED                       |           | 2            |             | 12/31/92         | 180 |                  |
| ORAL; TABLET, SUSTAINED ACTION                  |           | 2            |             | 01/27/87         | 600 |                  |
| ORAL-21; TABLET                                 |           | 1            |             |                  |     |                  |
| ORAL-28; TABLET                                 |           | 2            |             | 12/30/94         | 510 |                  |
| RECTAL; ENEMA                                   |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION                               |           | 1            |             |                  |     |                  |
| <b>SODIUM BICARBONATE</b>                       | 000144558 |              |             |                  |     |                  |
| BUCCAL; GUM, CHEWING                            |           | 1            |             |                  |     |                  |
| IM - IV; INJECTION                              |           | 1            |             |                  |     |                  |
| IM - IV; POWDER, FOR INJECTION SOLUTION         |           | 5            |             | 01/26/93         | 600 |                  |
| INTRAMUSCULAR; INJECTION                        |           | 1            |             |                  |     |                  |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                  |
| INTRAPERITONEAL; POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                  |
| INTRATHECAL; INJECTABLE                         |           | 2            |             | 12/07/89         | 160 | 0.04%            |
| INTRATHECAL; INJECTION                          |           | 1            |             |                  |     |                  |
| INTRAVENOUS; INJECTION                          |           | 11           |             | 04/13/95         | 520 | 0.05%            |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION     |           | 2            |             | 10/13/87         | 600 |                  |
| IV(INFUSION); INJECTION                         |           | 4            |             | 08/25/94         | 510 |                  |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION    |           | 6            |             | 10/22/93         | 520 |                  |
| ORAL; CAPSULE                                   |           | 4            |             | 12/31/93         | 510 | 4.0MG            |
| ORAL; CAPSULE, HARD GELATIN                     |           | 1            |             |                  |     |                  |
| ORAL; GRANULE, EFFERVESCENT                     |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION                                  |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                    |           | 11           |             | 11/30/95         | 600 | 1.0MG - 60.0MG   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,  |           | 4            |             | 03/31/94         | 180 | 65.0MG - 140.0MG |
| ORAL; TABLET, COATED                            |           | 5            |             | 02/25/92         | 600 | 0.63MG - 6.0MG   |
| ORAL; TABLET, FILM COATED                       |           | 4            |             | 09/28/77         | 600 | 0.867MG - 7.6MG  |
| <b>SODIUM BISULFATE</b>                         | 007681381 |              |             |                  |     |                  |
| IM - IV; INJECTION                              |           | 5            |             | 03/28/83         | 600 | 0.1% - 0.75%     |
| INHALATION; SOLUTION                            |           | 1            |             |                  |     |                  |
| ORAL; CONCENTRATE                               |           | 1            |             |                  |     |                  |
| <b>SODIUM BISULFITE</b>                         | 007631905 |              |             |                  |     |                  |
| EPIDURAL; INJECTION                             |           | 2            |             | 10/03/72         | UNK | 0.05% - 0.07%    |
| IM - IV - SC; INJECTION                         |           | 5            |             | 12/22/87         | 110 | 0.02% - 0.32%    |
| IM - IV; INJECTION                              |           | 44           |             | 10/31/94         | 600 | 0.00013% - 0.66% |
| INHALATION; SOLUTION                            |           | 7            |             | 06/03/83         | 600 | 0.011% - 0.3%    |
| INTRA-ARTICULAR; INJECTION                      |           | 8            |             | 05/24/82         | 600 | 0.1% - 0.32%     |
| INTRABURSAL; INJECTION                          |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                 | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| SODIUM BISULFITE                                | 007631905 |              |             |                  |     |                  |
| INTRACARDIAC; INJECTION                         |           | 2            |             | 01/06/76         | 600 | 0.1%             |
| INTRADERMAL; INJECTION, SUSTAINED ACTION        |           | 1            |             |                  |     |                  |
| INTRALESIONAL; INJECTION                        |           | 7            |             | 06/19/80         | 600 | 0.1% - 0.32%     |
| INTRAMUSCULAR; INJECTION                        |           | 13           |             | 07/26/86         | 600 | 0.05% - 0.66%    |
| INTRAPERITONEAL; INJECTION                      |           | 1            |             |                  |     |                  |
| INTRAPERITONEAL; SOLUTION                       |           | 2            |             | 01/29/86         | 160 |                  |
| INTRASYNOVIAL; INJECTION                        |           | 3            |             | 03/01/77         | UNK | 0.05% - 0.1%     |
| INTRAVENOUS; INJECTION                          |           | 5            |             | 10/02/87         | 600 | 0.3% - 0.35%     |
| INTRAVENOUS; SOLUTION, INJECTION                |           | 1            |             |                  |     |                  |
| IV(INFUSION); INJECTION                         |           | 41           |             | 02/21/95         | 600 | 0.02% - 10.0%    |
| NERVE BLOCK; INJECTION                          |           | 8            |             | 09/09/80         | 600 | 0.05% - 0.2%     |
| OPHTHALMIC; SOLUTION                            |           | 2            |             | 09/23/59         | UNK | 0.1%             |
| OPHTHALMIC; SUSPENSION                          |           | 2            |             | 05/30/73         | UNK | 0.06%            |
| ORAL; CAPSULE                                   |           | 4            |             | 06/14/79         | 120 |                  |
| ORAL; CONCENTRATE                               |           | 3            |             | 04/27/83         | 600 | 0.04993% - 0.25% |
| ORAL; SOLUTION                                  |           | 2            |             | 12/07/92         | UNK | 0.1%             |
| ORAL; SUSPENSION                                |           | 1            |             |                  |     |                  |
| ORAL; SYRUP                                     |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                    |           | 3            |             | 12/01/92         | UNK | 0.08MG - 0.23MG  |
| OTIC; SOLUTION                                  |           | 2            |             | 12/01/81         | 600 | 0.1%             |
| OTIC; SUSPENSION                                |           | 1            |             |                  |     |                  |
| SOFT TISSUE; INJECTION                          |           | 5            |             | 05/24/87         | 600 | 0.1% - 0.32%     |
| SUBCUTANEOUS; INJECTION                         |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM                        |           | 5            |             | 09/04/92         | UNK | 0.1% - 0.3%      |
| TOPICAL; POWDER, FOR RECONSTITUTION             |           | 1            |             |                  |     |                  |
| SODIUM BORATE                                   | 001303964 |              |             |                  |     |                  |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION          |           | 2            |             | 12/09/53         | UNK |                  |
| OPHTHALMIC; SOLUTION                            |           | 4            |             | 06/08/94         | UNK | 0.042% - 0.3%    |
| OPHTHALMIC; SUSPENSION                          |           | 1            |             |                  |     |                  |
| OTIC; SOLUTION                                  |           | 1            |             |                  |     |                  |
| SODIUM BORATE DECAHYDRATE                       | 001344907 |              |             |                  |     |                  |
| OPHTHALMIC; SOLUTION                            |           | 1            |             |                  |     |                  |
| SODIUM CARBONATE                                | 000497198 |              |             |                  |     |                  |
| BUCCAL; GUM, CHEWING                            |           | 1            |             |                  |     |                  |
| IM - IV; INJECTION                              |           | 1            |             |                  |     |                  |
| IM - IV; POWDER, FOR INJECTION SOLUTION         |           | 8            |             | 11/30/92         | 600 |                  |
| INTRA-ARTERIAL; SOLUTION, INJECTION             |           | 1            |             |                  |     |                  |
| INTRAMUSCULAR; INJECTION                        |           | 1            |             |                  |     |                  |
| INTRAPERITONEAL; POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                  |
| INTRAPLEURAL; POWDER, FOR INJECTION SOLUTION    |           | 1            |             |                  |     |                  |
| INTRATUMOR; POWDER, FOR INJECTION SOLUTION      |           | 1            |             |                  |     |                  |
| INTRAVASCULAR; INJECTION                        |           | 2            |             | 07/07/80         | 600 |                  |
| INTRAVASCULAR; SOLUTION, INJECTION              |           | 1            |             |                  |     |                  |
| INTRAVENOUS; INJECTION                          |           | 2            |             | 11/20/85         | 600 |                  |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION     |           | 1            |             |                  |     |                  |
| INTRAVENOUS; SOLUTION, INJECTION                |           | 1            |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                 | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| SODIUM CARBONATE                                | 000497198 | 3            |             | 10/31/93         | 600 |                  |
| IV(INFUSION); INJECTION                         |           | 2            |             | 09/10/85         | 600 |                  |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION    |           | 1            |             |                  |     |                  |
| NERVE BLOCK; INJECTION                          |           | 11           |             | 10/31/95         | 600 |                  |
| OPHTHALMIC; SOLUTION                            |           | 3            |             | 02/27/85         | 600 | 1.0MG - 6.0MG    |
| ORAL; CAPSULE, SUSTAINED ACTION                 |           | 3            |             | 07/21/95         | 600 | 10.4MG - 87.5MG  |
| ORAL; TABLET                                    |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                       |           | 1            |             |                  |     |                  |
| RECTAL; SUSPENSION                              |           | 1            |             |                  |     |                  |
| SODIUM CARBONATE HYDRATE                        | 005968116 | 1            |             |                  |     |                  |
| INTRA-ARTERIAL; INJECTION                       |           | 1            |             |                  |     |                  |
| INTRACARDIAC; INJECTION                         |           | 1            |             |                  |     |                  |
| INTRAVENOUS; INJECTION                          |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION                            |           | 1            |             |                  |     |                  |
| SODIUM CARRAGENATE                              |           | 1            |             |                  |     |                  |
| ORAL; SYRUP                                     |           | 2            |             | 10/15/80         | UNK | 10.0MG - 150.0MG |
| SODIUM CELLULOSE                                | 007775099 | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                   |           | 1            |             |                  |     |                  |
| SODIUM CHLORATE                                 | 007647145 | 16           |             | 10/13/87         | 600 | 0.21% - 0.855%   |
| INTRAMUSCULAR; INJECTION                        |           | 2            |             | 10/10/84         | 600 | 0.4% - 0.6%      |
| NERVE BLOCK; INJECTION                          |           | 38           |             | 02/26/93         | 600 | 0.0006% - 0.9%   |
| EPIDURAL; INJECTION                             |           | 47           |             | 04/11/89         | 600 | 0.1% - 0.9%      |
| IM - IV - SC; INJECTION                         |           | 60           |             | 12/27/94         | 600 | 0.08% - 1.2%     |
| IM - IV; INJECTION                              |           | 8            |             | 12/27/91         | 600 |                  |
| IM - IV; POWDER, FOR INJECTION SOLUTION         |           | 17           |             | 04/14/95         | 600 | 0.25% - 9.0%     |
| IM - SC; INJECTION                              |           | 34           |             | 09/26/95         | 600 | 0.02% - 0.9%     |
| INHALATION; SOLUTION                            |           | 8            |             | 08/23/91         | 600 | 0.26% - 1.2%     |
| INTRA-ARTERIAL; INJECTION                       |           | 21           |             | 05/24/82         | 600 | 0.2% - 0.9%      |
| INTRA-ARTICULAR; INJECTION                      |           | 5            |             | 02/13/74         | 600 | 0.66% - 0.9%     |
| INTRABURSAL; INJECTION                          |           | 4            |             | 01/06/74         | 600 | 0.45% - 0.7%     |
| INTRACARDIAC; INJECTION                         |           | 1            |             |                  |     |                  |
| INTRACAVITARY; POWDER, FOR INJECTION SOLUTION   |           | 4            |             | 10/16/87         | UNK | 0.2% - 0.7%      |
| INTRADERMAL; INJECTION                          |           | 7            |             | 10/16/87         | UNK | 0.2% - 0.9%      |
| INTRALESIONAL; INJECTION                        |           | 47           |             | 01/27/85         | 600 | 0.0017% - 0.9%   |
| INTRAMUSCULAR; INJECTION                        |           | 1            |             |                  |     |                  |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION   |           | 2            |             | 04/11/95         | UNK | 0.85% - 0.9%     |
| INTRAMUSCULAR; SOLUTION, INJECTION              |           | 2            |             | 04/28/95         | 600 | 0.64%            |
| INTRAOCULAR; SOLUTION                           |           | 4            |             | 07/03/84         | 600 |                  |
| INTRAPERITONEAL; POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                  |
| INTRAPERITONEAL; SOLUTION                       |           | 4            |             | 07/03/86         | 600 |                  |
| INTRAPLEURAL; POWDER, FOR INJECTION SOLUTION    |           | 10           |             | 11/05/81         | 600 | 0.2% - 0.9%      |
| INTRASYNOVIAL; INJECTION                        |           | 3            |             | 06/17/92         | 120 | 0.85% - 0.9%     |
| INTRATHECAL; INJECTABLE                         |           | 17           |             | 10/30/92         | UNK | 0.26% - 0.9%     |
| INTRATHECAL; INJECTION                          |           |              |             |                  |     |                  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| SODIUM CHLORIDE                                | 007647145 |              |             |                  |     |                   |
| INTRATRACHEAL; INJECTION                       |           | 1            |             |                  |     |                   |
| INTRATRACHEAL; POWDER, FOR RECONSTITUTION      |           | 1            |             |                  |     |                   |
| INTRATRACHEAL; SUSPENSION                      |           | 1            |             |                  |     |                   |
| INTRATUMOR; INJECTION                          |           | 3            |             | 07/08/88         | 600 | 0.26% - 1.2%      |
| INTRATUMOR; POWDER, FOR INJECTION SOLUTION     |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                         |           | 146          |             | 01/28/95         | 600 | 0.0006% - 4.5%    |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 7            |             | 02/07/95         | 180 |                   |
| INTRAVENOUS; SOLUTION                          |           | 4            |             | 11/16/76         | 160 | 0.9%              |
| IONTOPHORESIS; SOLUTION                        |           | 1            |             |                  |     |                   |
| IV - SC; INJECTION                             |           | 17           |             | 10/10/95         | 600 | 0.1% - 0.9%       |
| IV - SC; POWDER, FOR INJECTION SOLUTION        |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                        |           | 64           |             | 02/28/95         | 600 | 0.0006% - 90.0%   |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 8            |             | 09/20/95         | 180 |                   |
| IV(INFUSION); SOLUTION, INJECTION              |           | 3            |             | 12/28/95         | 110 | 0.89% - 0.9%      |
| IV(INFUSION); SUSPENSION, INJECTION            |           | 5            |             |                  |     |                   |
| NASAL; SOLUTION                                |           | 1            |             | 12/26/90         | 510 | 0.5% - 0.9%       |
| NASAL; SPRAY                                   |           | 1            |             |                  |     |                   |
| NASAL; SPRAY, METERED                          |           | 6            |             | 10/20/95         | UNK | 0.65%             |
| NERVE BLOCK; INJECTION                         |           | 77           |             | 06/23/95         | 600 | 0.21% - 0.9%      |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION         |           | 4            |             | 09/22/93         | UNK |                   |
| OPHTHALMIC; SOLUTION                           |           | 65           |             | 09/29/95         | 600 | 0.08% - 0.9%      |
| OPHTHALMIC; SUSPENSION                         |           | 19           |             | 09/13/95         | 600 | 0.018% - 0.85%    |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                   |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 5            |             | 12/23/91         | 520 | 0.05% - 0.4%      |
| ORAL; SOLUTION                                 |           | 10           |             | 06/01/94         | 600 | 0.9%              |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                               |           | 6            |             | 09/15/95         | 180 | 0.1% - 2.0%       |
| ORAL; SYRUP                                    |           | 4            |             | 12/30/88         | 180 | 0.05% - 0.2%      |
| ORAL; TABLET                                   |           | 4            |             | 07/17/87         | 600 | 10.0MG - 148.0MG  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 5            |             | 04/26/94         | 510 | 17.5MG - 143.26MG |
| OTIC; SOLUTION                                 |           | 2            |             | 01/16/85         | 600 | 0.4% - 0.7%       |
| PERIDURAL; INJECTION                           |           | 1            |             |                  |     |                   |
| RECTAL; SOLUTION                               |           | 1            |             |                  |     |                   |
| RECTAL; SUPPOSITORY                            |           | 2            |             | 08/31/92         | 600 |                   |
| SOFT TISSUE; INJECTION                         |           | 6            |             | 05/24/82         | 600 | 0.667% - 0.9%     |
| SUBCUTANEOUS; INJECTION                        |           | 20           |             | 12/22/94         | 180 | 0.35% - 0.9%      |
| SUBCUTANEOUS; SOLUTION, INJECTION              |           | 2            |             | 12/29/95         | 510 | 0.877% - 0.9%     |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION                              |           | 2            |             | 06/13/74         | UNK | 0.68%             |
| SODIUM CHLORIDE INJECTION                      |           |              |             |                  |     |                   |
| INTRAVENOUS; INJECTION                         |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                                     | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|---|-----------|--------------|-------------|------------------|-----|------------------|
| SODIUM CHLORIDE INJECTION, BACTERIOSTATIC<br>INTRAVENOUS; INJECTION |           | 2            |             | 12/29/89         | 160 |                  |
| SODIUM CITRATE  | 006132043 |              |             |                  |     |                  |
| EPIDURAL; INJECTION   |           | 1            |             |                  |     |                  |
| IM - IV - SC; INJECTION   |           | 11           |             | 08/23/95         | 600 | 0.047% - 1.0%    |
| IM - IV; INJECTION  |           | 39           |             | 12/14/95         | 600 | 0.0005% - 2.9%   |
| IM - IV; POWDER, FOR INJECTION SOLUTION                             |           | 4            |             | 10/26/88         | 600 |                  |
| IM - SC; INJECTION  |           | 1            |             |                  |     |                  |
| INHALATION; SOLUTION  |           | 4            |             | 07/21/92         | 600 | 0.1%             |
| INTRA-ARTERIAL; INJECTION   |           | 1            |             |                  |     |                  |
| INTRA-ARTICULAR; INJECTION  |           | 8            |             | 04/09/86         | 600 | 0.1% - 1.0%      |
| INTRACARDIAC; INJECTION   |           | 3            |             | 01/06/76         | 600 | 0.04% - 0.32%    |
| INTRACAVITARY; POWDER, FOR INJECTION SOLUTION, LYOPHILI             |           | 1            |             |                  |     |                  |
| INTRALESIONAL; INJECTION  |           | 6            |             | 02/17/84         | 600 | 0.1% - 1.0%      |
| INTRAMUSCULAR; INJECTION  |           | 20           |             | 06/26/95         | 600 | 0.05% - 2.848%   |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION                       |           | 1            |             |                  |     |                  |
| INTRAOCULAR; SOLUTION   |           | 2            |             | 04/28/95         | 600 | 0.17%            |
| INTRAPERITONEAL; INJECTION  |           | 1            |             |                  |     |                  |
| INTRAPLEURAL; INJECTION   |           | 1            |             |                  |     |                  |
| INTRASYNOVIAL; INJECTION  |           | 3            |             | 02/17/84         | 600 | 0.1% - 1.0%      |
| INTRATHECAL; INJECTION  |           | 1            |             |                  |     |                  |
| INTRAUTERINE; SOLUTION  |           | 1            |             |                  |     |                  |
| INTRAVASCULAR; INJECTION  |           | 2            |             | 09/29/89         | 160 | 0.32%            |
| INTRAVENOUS; INJECTION  |           | 16           |             | 08/18/95         | 110 | 0.015% - 2.875%  |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                         |           | 1            |             |                  |     |                  |
| IV(INFUSION); INJECTION   |           | 28           |             | 08/18/95         | 110 | 0.023% - 2.848%  |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION                        |           | 2            |             | 12/19/86         | 600 | 40.0MG - 80.0MG  |
| IV(INFUSION); SOLUTION, INJECTION                                   |           | 2            |             | 12/29/92         | 520 | 0.125% - 0.25%   |
| NASAL; SOLUTION   |           | 1            |             |                  |     |                  |
| NASAL; SPRAY  |           | 1            |             |                  |     |                  |
| NASAL; SPRAY, METERED   |           | 2            |             | 03/08/95         | UNK |                  |
| NERVE BLOCK; INJECTION  |           | 1            |             |                  |     |                  |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                              |           | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION  |           | 6            |             | 01/04/95         | 600 | 0.45% - 2.0%     |
| OPHTHALMIC; SUSPENSION  |           | 3            |             | 06/10/88         | UNK | 0.3% - 0.45%     |
| ORAL; CONCENTRATE   |           | 4            |             | 07/20/88         | 600 | 0.06262% - 0.3%  |
| ORAL; DROPS   |           | 2            |             | 12/18/80         | 600 |                  |
| ORAL; GRANULE   |           | 5            |             | 06/15/88         | 600 |                  |
| ORAL; GRANULE, FOR RECONSTITUTION                                   |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION                                    |           | 31           |             | 12/23/93         | 530 |                  |
| ORAL; SOLUTION  |           | 11           |             | 10/31/93         | 600 | 0.4% - 1.5%      |
| ORAL; SOLUTION, ELIXIR  |           | 4            |             | 10/10/86         | 600 |                  |
| ORAL; SUSPENSION  |           | 18           |             | 02/28/94         | 600 | 0.35% - 0.5%     |
| ORAL; SYRUP   |           | 51           |             | 09/30/94         | 600 | 0.1% - 3.94%     |
| ORAL; TABLET  |           | 6            |             | 11/05/92         | 600 | 48.0MG - 110.6MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                      |           | 5            |             | 09/11/95         | 600 | 95.0MG - 300.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                        |           | 3            |             | 05/15/90         | 600 | 10.0MG - 82.0MG  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| SODIUM CITRATE                                 | 006132043 | 2            |             | 08/31/81         | 600 |                 |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                 |
| ORAL-28; TABLET                                |           | 1            |             |                  |     |                 |
| OTIC; SOLUTION                                 |           | 2            |             | 09/02/81         | 600 | 0.4%            |
| RECTAL; SOLUTION                               |           | 2            |             | 06/19/80         | 600 | 1.0%            |
| SOFT TISSUE; INJECTION                         |           | 9            |             | 08/03/94         | 600 | 0.05% - 1.0%    |
| TOPICAL; EMULSION, CREAM                       |           | 2            |             | 11/12/64         | 600 |                 |
| TOPICAL; LOTION                                |           | 1            |             |                  |     |                 |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                 |
| URETERAL; SOLUTION                             |           | 1            |             |                  |     |                 |
| SODIUM CITRATE ANHYDROUS                       | 000068042 | 4            |             | 03/08/79         | 600 | 0.36% - 5.0%    |
| IM - IV; INJECTION                             |           | 1            |             |                  |     |                 |
| INTRA-ARTICULAR; INJECTION                     |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                         |           | 1            |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                        |           | 1            |             |                  |     |                 |
| ORAL; GRANULE                                  |           | 1            |             |                  |     |                 |
| ORAL; GRANULE, EFFERVESCENT                    |           | 1            |             |                  |     |                 |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 3            |             | 02/10/89         | 600 | 0.28% - 2.2%    |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                   |           | 2            |             | 04/28/80         | 600 | 11.0MG - 28.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                 |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                 |
| SOFT TISSUE; INJECTION                         |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                 |
| SODIUM CITRATE DIHYDRATE                       |           | 1            |             |                  |     |                 |
| IM - IV; INJECTION                             |           | 1            |             |                  |     |                 |
| SODIUM DESOXYCHOLATE                           |           | 2            |             | 03/31/95         | 600 | 41.0MG          |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                 |
| SODIUM DITHIONITE                              | 007775146 | 1            |             |                  |     |                 |
| IM - IV - SC; INJECTION                        |           | 2            |             | 12/19/91         | 510 |                 |
| INTRAVENOUS; INJECTION                         |           | 15           |             | 12/19/91         | 510 | 3.0%            |
| IV(INFUSION); INJECTION                        |           | 1            |             |                  |     |                 |
| SODIUM DODECYLBENZENESULFONATE                 | 012068212 | 1            |             |                  |     |                 |
| TOPICAL; SUSPENSION, SHAMPOO                   |           | 9            |             | 03/08/79         | 600 | 0.075% - 0.1%   |
| SODIUM FORMALDEHYDE SULFOXYLATE                | 000149440 | 1            |             |                  |     |                 |
| IM - IV; INJECTION                             |           | 1            |             |                  |     |                 |
| IM - SC; INJECTION                             |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; INJECTION                       |           | 1            |             |                  |     |                 |
| IV(INFUSION); INJECTION                        |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                 |
| SODIUM HEXAMETAPHOSPHATE                       | 010124568 | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                 |
| SODIUM HYDROXIDE                               | 001310732 | 16           |             | 10/13/87         | 600 |                 |
| CAUDAL BLOCK; INJECTION                        |           | 2            |             | 10/10/84         | 600 |                 |
| DENTAL; INJECTION                              |           | 1            |             |                  |     |                 |
| DENTAL; SOLUTION                               |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                            | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| SODIUM HYDROXIDE   | 001310732 |              |             |                  |     |                 |
| EPIDURAL; INJECTION  |           | 34           |             | 10/30/92         | UNK |                 |
| IM - IV - SC; INJECTION                                    |           | 27           |             | 12/29/92         | UNK |                 |
| IM - IV - SC; POWDER, FOR INJECTION SOLUTION               |           | 1            |             |                  |     |                 |
| IM - IV; INJECTION   |           | 171          |             | 12/27/94         | 600 | 0.134% - 1.0%   |
| IM - IV; POWDER, FOR INJECTION SOLUTION                    |           | 12           |             | 10/30/95         | 600 |                 |
| IM - IV; SOLUTION, INJECTION                               |           | 3            |             | 03/05/90         | 600 |                 |
| IM - SC; INJECTION   |           | 10           |             | 04/14/95         | 600 |                 |
| IM - SC; INJECTION, SUSTAINED ACTION                       |           | 1            |             |                  |     |                 |
| IM - SC; POWDER, FOR INJECTION SOLUTION                    |           | 1            |             |                  |     |                 |
| INHALATION; AEROSOL, METERED                               |           | 1            |             |                  |     |                 |
| INHALATION; SOLUTION                                       |           | 22           |             | 07/28/95         | 600 | 0.1498% - 2.33% |
| INTERSTITIAL; INJECTION                                    |           | 1            |             |                  |     |                 |
| INTRA-ARTERIAL; INJECTION                                  |           | 12           |             | 08/23/91         | 600 | 0.8%            |
| INTRA-ARTERIAL; SOLUTION, INJECTION                        |           | 1            |             |                  |     |                 |
| INTRA-ARTICULAR; INJECTION                                 |           | 26           |             | 04/09/86         | 600 |                 |
| INTRABURSAL; INJECTION                                     |           | 5            |             | 02/13/74         | 600 |                 |
| INTRACARDIAC; INJECTION                                    |           | 3            |             | 06/01/88         | 600 |                 |
| INTRACAVITARY; INJECTION                                   |           | 1            |             |                  |     |                 |
| INTRACAVITARY; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED |           | 1            |             |                  |     |                 |
| INTRADERMAL; INJECTION                                     |           | 5            |             | 10/16/87         | UNK |                 |
| INTRALESIONAL; INJECTION                                   |           | 15           |             | 10/16/87         | UNK |                 |
| INTRAMUSCULAR; INJECTION                                   |           | 82           |             | 01/27/95         | 600 | 2.76%           |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION              |           | 4            |             | 02/27/85         | UNK |                 |
| INTRAMUSCULAR; SOLUTION, INJECTION                         |           | 1            |             |                  |     |                 |
| INTRAOCULAR; SOLUTION                                      |           | 2            |             | 04/28/95         | 600 |                 |
| INTRAPERITONEAL; INJECTION                                 |           | 1            |             |                  |     |                 |
| INTRAPERITONEAL; SOLUTION                                  |           | 3            |             | 08/19/97         | 160 |                 |
| INTRAPLEURAL; INJECTION                                    |           | 1            |             |                  |     |                 |
| INTRASYNOVIAL; INJECTION                                   |           | 9            |             | 02/11/84         | 600 |                 |
| INTRATHECAL; INJECTABLE                                    |           | 1            |             |                  |     |                 |
| INTRATHECAL; INJECTION                                     |           | 14           |             | 10/30/92         | UNK |                 |
| INTRATHECAL; POWDER, FOR INJECTION SOLUTION                |           | 2            |             | 12/21/87         | 150 |                 |
| INTRATHECAL; SOLUTION                                      |           | 1            |             |                  |     |                 |
| INTRATRACHEAL; INJECTION                                   |           | 1            |             |                  |     |                 |
| INTRATRACHEAL; POWDER, FOR RECONSTITUTION                  |           | 1            |             |                  |     |                 |
| INTRATRACHEAL; SUSPENSION                                  |           | 1            |             |                  |     |                 |
| INTRATUMOR; INJECTION                                      |           | 3            |             | 01/08/88         | 600 | 0.8%            |
| INTRATUMOR; POWDER, FOR INJECTION SOLUTION                 |           | 1            |             |                  |     |                 |
| INTRAUTERINE; INJECTION                                    |           | 1            |             |                  |     |                 |
| INTRAVASCULAR; INJECTION                                   |           | 4            |             | 01/22/92         | 160 |                 |
| INTRAVASCULAR; SOLUTION                                    |           | 1            |             |                  |     |                 |
| INTRAVENOUS; EMULSION, INJECTION                           |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION                                     |           | 187          |             | 08/18/95         | 110 | 0.05% - 10.0%   |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                |           | 19           |             | 04/19/95         | 600 |                 |
| INTRAVENOUS; SOLUTION                                      |           | 6            |             | 12/26/85         | 160 | 1.0%            |
| INTRAVENOUS; SUSPENSION, INJECTION                         |           | 1            |             |                  |     |                 |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| SODIUM HYDROXIDE                             | 001310732 |              |             |                  |     |                   |
| IRRIGATION; SOLUTION                         |           | 4            |             | 11/27/91         | 600 |                   |
| IV - SC; INJECTION                           |           | 24           |             | 10/10/95         | 600 |                   |
| IV - SC; POWDER, FOR INJECTION SOLUTION      |           | 2            |             | 08/31/90         | 600 |                   |
| IV(INFUSION); INJECTION                      |           | 184          |             | 10/27/95         | 510 | 0.05% - 10.5%     |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION |           | 13           |             | 09/20/95         | 180 |                   |
| IV(INFUSION); SOLUTION                       |           | 1            |             |                  |     |                   |
| NASAL; SPRAY, METERED                        |           | 6            |             | 10/20/95         | UNK |                   |
| NERVE BLOCK; INJECTION                       |           | 72           |             | 06/23/95         | 400 | 0.67%             |
| OPHTHALMIC; GEL                              |           | 1            |             |                  |     |                   |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION       |           | 3            |             | 04/02/63         | UNK |                   |
| OPHTHALMIC; SOLUTION                         |           | 59           |             | 12/29/95         | 600 | 0.1%              |
| OPHTHALMIC; SUSPENSION                       |           | 22           |             | 09/13/95         | 600 |                   |
| ORAL; CONCENTRATE                            |           | 5            |             | 10/16/87         | 600 |                   |
| ORAL; SOLUTION                               |           | 46           |             | 10/24/95         | 160 | 1.0% - 2.33%      |
| ORAL; SUSPENSION                             |           | 7            |             | 02/28/94         | 600 | 40.0%             |
| ORAL; SYRUP                                  |           | 13           |             | 09/25/95         | 600 |                   |
| ORAL; TABLET                                 |           | 2            |             | 08/01/94         | 400 | 0.45MG            |
| ORAL; TABLET, COATED                         |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 2            |             |                  |     |                   |
| OTIC; SOLUTION                               |           | 4            |             | 10/14/94         | UNK |                   |
| PERFUSION/CARDIAC; SOLUTION                  |           | 1            |             | 12/29/95         | 600 | 0.049% - 0.56%    |
| PERIDURAL; INJECTION                         |           | 1            |             |                  |     |                   |
| RECTAL; ENEMA                                |           | 1            |             |                  |     |                   |
| RECTAL; SOLUTION                             |           | 1            |             |                  |     |                   |
| RETROBULBAR; INJECTION                       |           | 8            |             | 10/24/95         | 140 |                   |
| SOFT TISSUE; INJECTION                       |           | 1            |             |                  |     |                   |
| SPINAL; INJECTION                            |           | 10           |             | 05/24/82         | 600 |                   |
| SUBCONJUNCTIVAL; INJECTION                   |           | 6            |             | 12/11/87         | 400 |                   |
| SUBCUTANEOUS; INJECTION                      |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION |           | 19           |             | 03/31/94         | 510 |                   |
| TOPICAL; CREAM, AUGMENTED                    |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                   |
| TOPICAL; GEL                                 |           | 32           |             | 09/20/95         | UNK | 0.00668% - 0.283% |
| TOPICAL; GEL, JELLY                          |           | 6            |             | 04/29/94         | UNK |                   |
| TOPICAL; LOTION                              |           | 3            |             | 04/29/93         | 600 |                   |
| TOPICAL; LOTION, AUGMENTED                   |           | 25           |             | 09/30/94         | 400 | 0.004% - 2.8%     |
| TOPICAL; OINTMENT                            |           | 1            |             |                  |     |                   |
| TOPICAL; SHAMPOO                             |           | 2            |             | 02/03/87         | 600 |                   |
| TOPICAL; SOLUTION                            |           | 1            |             |                  |     |                   |
| TOPICAL; SPONGE                              |           | 18           |             |                  |     |                   |
| TRANSDERMAL; FILM, CONTROLLED RELEASE        |           | 3            |             | 12/15/95         | 600 | 0.0213%           |
| URETERAL; SOLUTION                           |           | 1            |             | 01/07/87         | 520 |                   |
| VAGINAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                   |
| VAGINAL; GEL                                 |           | 2            |             | 12/21/95         | 520 | 0.18813%          |
|  |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| SODIUM HYPOCHLORITE<br>IV(INFUSION); INJECTION                                   | 007681529 | 1            |             |                  |     |                  |
| ORAL; SUSPENSION   |           | 1            |             |                  |     |                  |
| SODIUM IODIDE<br>INTRAVENOUS; POWDER, FOR INJECTION SOLUTION                     | 007681825 | 1            |             |                  |     |                  |
| SODIUM L-CYSTEINATE HYDROCHLORIDE<br>INTRADISCAL; POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                  |
| SODIUM L-LACTATE<br>EPIDURAL; INJECTION  | 000867561 | 1            |             |                  |     |                  |
| IM - IV - SC; INJECTION  |           | 2            |             | 01/06/76         | 600 | 0.18%            |
| IM - IV; INJECTION   |           | 1            |             |                  |     |                  |
| INTRACARDIAC; INJECTION  |           | 2            |             | 01/06/76         | 600 | 0.18%            |
| IV(INFUSION); INJECTION  |           | 2            |             | 01/06/76         | 600 | 0.18%            |
| NERVE BLOCK; INJECTION   |           | 1            |             |                  |     |                  |
| SODIUM LACTATE<br>CAUDAL BLOCK; INJECTION  | 000072173 | 1            |             |                  |     |                  |
| IM - IV - SC; INJECTION  |           | 1            |             |                  |     |                  |
| INTRACARDIAC; INJECTION  |           | 1            |             |                  |     |                  |
| INTRAPERITONEAL; SOLUTION  |           | 1            |             |                  |     |                  |
| NERVE BLOCK; INJECTION   |           | 1            |             |                  |     |                  |
| TOPICAL; SOLUTION  |           | 1            |             |                  |     |                  |
| SODIUM LAURETH SULFATE<br>ORAL; CAPSULE  | 001335724 | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED   |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM   |           | 1            |             |                  |     |                  |
| SODIUM LAURETH-5 SULFATE<br>TOPICAL; EMULSION, CREAM                             | 009004824 | 1            |             |                  |     |                  |
| TOPICAL; SHAMPOO   |           | 1            |             |                  |     |                  |
| SODIUM LAUROYL SARCOSINATE<br>TOPICAL; LOTION                                    | 000137166 | 1            |             |                  |     |                  |
| SODIUM LAURYL SULFATE<br>BUCCAL/SUBLINGUAL; TABLET                               | 000151213 | 1            |             |                  |     |                  |
| DENTAL; GEL  |           | 1            |             |                  |     |                  |
| DENTAL; PASTE  |           | 1            |             |                  |     |                  |
| ORAL; CAPLET   |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE  |           | 246          |             | 12/20/95         | 520 | 0.15MG - 308.0MG |
| ORAL; CAPSULE, ENTERIC COATED PELLETS  |           | 1            |             |                  |     |                  |
| ORAL; CAPSULE, HARD GELATIN  |           | 5            |             | 05/03/95         | 530 |                  |
| ORAL; CAPSULE, SUSTAINED ACTION  |           | 17           |             | 04/25/95         | UNK | 0.004MG - 0.6MG  |
| ORAL; DROPS  |           | 1            |             |                  |     |                  |
| ORAL; GRANULE  |           | 1            |             |                  |     |                  |
| ORAL; POWDER, FOR RECONSTITUTION   |           | 11           |             | 04/28/95         | 600 | 0.01% - 0.066%   |
| ORAL; SUSPENSION   |           | 2            |             | 01/05/78         | 520 |                  |
| ORAL; TABLET   |           | 317          |             | 10/06/95         | UNK | 0.025MG - 50.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                                   |           | 5            |             | 01/04/95         | 600 | 0.5MG - 5.0MG    |
| ORAL; TABLET, COATED   |           | 10           |             | 06/23/95         | 600 | 0.5MG - 4.0MG    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED                                     |           | 3            |             | 05/15/90         | 600 | 5.39MG - 8.09MG  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---|-----------|--------------|-------------|------------------|-----|-----------------|
| SODIUM LAURYL SULFATE                         | 000151213 | 21           |             | 05/30/95         | 600 | 0.13MG - 4.5MG  |
| ORAL; TABLET, FILM COATED                     |           | 5            |             | 11/25/91         | 600 | 1.76MG - 15.0MG |
| ORAL; TABLET, SUSTAINED ACTION                |           | 3            |             | 07/07/80         | 600 | 0.01MG - 0.02MG |
| SUBLINGUAL; TABLET                            |           | 12           |             | 09/28/92         | 600 | 0.1% - 2.5%     |
| TOPICAL; EMULSION, CREAM                      |           | 5            |             | 01/24/92         | 600 | 0.25%           |
| TOPICAL; LOTION                               |           | 2            |             | 08/08/83         | UNK | 0.15% - 1.0%    |
| TOPICAL; OINTMENT                             |           | 1            |             |                  |     |                 |
| TOPICAL; SPONGE                               |           | 2            |             | 01/10/91         | 600 |                 |
| TOPICAL; SUSPENSION, SHAMPOO                  |           | 3            |             | 09/19/85         | 600 | 0.3% - 0.333%   |
| VAGINAL; EMULSION, CREAM                      |           |              |             |                  |     |                 |
| SODIUM LAURYL SULFOACETATE                    | 001847581 | 1            |             |                  |     |                 |
| TOPICAL; SHAMPOO                              |           |              |             |                  |     |                 |
| SODIUM METABISULFITE                          | 007757746 | 4            |             | 10/13/87         | 600 | 0.05% - 0.183%  |
| CAUDAL BLOCK; INJECTION                       |           | 6            |             | 02/26/93         | 600 | 0.05% - 0.183%  |
| EPIDURAL; INJECTION                           |           | 5            |             | 04/10/89         | 600 | 0.1% - 0.15%    |
| IM - IV - SC; INJECTION                       |           | 37           |             | 12/16/95         | 600 | 0.007% - 0.66%  |
| IM - IV; INJECTION                            |           | 1            |             |                  |     |                 |
| INHALATION; SOLUTION                          |           | 2            |             | 11/15/74         | 600 | 0.09% - 0.1%    |
| INTRACARDIAC; INJECTION                       |           | 16           |             | 06/26/95         | 600 | 0.0025% - 0.66% |
| INTRAMUSCULAR; INJECTION                      |           | 22           |             | 05/18/92         | 600 | 0.01% - 0.32%   |
| INTRAVENOUS; INJECTION                        |           | 1            |             |                  |     |                 |
| INTRAVENOUS; SOLUTION, INJECTION              |           | 1            |             |                  |     |                 |
| IONTOPHORESIS; SOLUTION                       |           | 48           |             | 06/26/95         | 600 | 0.024% - 1.0%   |
| IV(INFUSION); INJECTION                       |           | 33           |             | 02/26/93         | 600 | 0.05% - 0.5%    |
| NERVE BLOCK; INJECTION                        |           | 6            |             | 03/06/94         | 600 | 0.01% - 0.3%    |
| OPHTHALMIC; SOLUTION                          |           | 1            |             |                  |     |                 |
| OPHTHALMIC; SUSPENSION                        |           | 2            |             | 08/30/91         | 600 | 0.36MG          |
| ORAL; CAPSULE                                 |           | 3            |             | 12/10/81         | 600 | 0.1% - 0.2%     |
| ORAL; CONCENTRATE                             |           | 1            |             |                  |     |                 |
| ORAL; SUSPENSION                              |           | 1            |             |                  |     |                 |
| ORAL; SYRUP                                   |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                  |           | 6            |             | 01/15/86         | 600 | 0.2MG - 4.1MG   |
| SODIUM PHOSPHATE                              | 007632055 | 8            |             | 07/22/82         | 600 | 0.3% - 1.0%     |
| IM - IV; INJECTION                            |           | 3            |             | 05/28/81         | 600 |                 |
| IM - IV; POWDER, FOR INJECTION SOLUTION       |           | 1            |             |                  |     |                 |
| IM - IV; SOLUTION, INJECTION                  |           | 2            |             | 02/27/79         | 600 | 0.58% - 1.0%    |
| INTRA-ARTICULAR; INJECTION                    |           | 3            |             | 02/08/77         | 510 | 0.25%           |
| INTRADERMAL; INJECTION                        |           | 1            |             |                  |     |                 |
| INTRALESIONAL; INJECTION                      |           | 4            |             | 01/01/85         | 600 | 0.29% - 0.58%   |
| INTRAMUSCULAR; INJECTION                      |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION |           | 4            |             | 12/24/81         | 600 | 0.16%           |
| INTRAVENOUS; INJECTION                        |           | 1            |             |                  |     |                 |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION   |           | 7            |             | 12/20/84         | 600 | 0.18%           |
| IV(INFUSION); INJECTION                       |           | 2            |             | 10/04/62         | UNK |                 |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION  |           | 1            |             |                  |     |                 |
| NASAL; SOLUTION                               |           | 8            |             | 03/31/95         | UNK | 0.075% - 0.81%  |
| OPHTHALMIC; SOLUTION                          |           |              |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                           | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| SODIUM PHOSPHATE  | 007632055 |              |             |                  |     |                   |
| OPHTHALMIC; SUSPENSION                                    |           | 3            |             | 07/21/81         | 600 | 0.2%              |
| ORAL; CAPSULE   |           | 1            |             |                  |     |                   |
| ORAL; CONCENTRATE   |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION  |           | 3            |             | 08/18/78         | 160 |                   |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                   |
| ORAL; SYRUP   |           | 2            |             | 10/31/93         | 600 |                   |
| SOFT TISSUE; INJECTION                                    |           | 2            |             | 02/27/79         | 600 | 0.58% - 1.0%      |
| SUBCUTANEOUS; INJECTION                                   |           | 4            |             | 05/30/86         | 510 | 0.24% - 0.378%    |
| TOPICAL; LOTION   |           | 2            |             | 03/30/89         | UNK | 0.2%              |
| TOPICAL; OINTMENT   |           | 1            |             |                  |     |                   |
| TOPICAL; SUSPENSION, SHAMPOO                              |           | 1            |             |                  |     |                   |
| SODIUM PHOSPHATE DIHYDRATE                                |           |              |             |                  |     |                   |
| IM - SC; INJECTION  |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; INJECTION                                   |           | 3            |             | 07/01/91         | 510 | 0.24%             |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED |           | 1            |             |                  |     |                   |
| SODIUM PHOSPHATE, DIBASIC                                 | 007782856 |              |             |                  |     |                   |
| IM - IV - SC; INJECTION                                   |           | 1            |             |                  |     |                   |
| IM - IV; INJECTION  |           | 21           |             | 05/09/91         | 600 | 0.24% - 1.746%    |
| IM - IV; POWDER, FOR INJECTION SOLUTION                   |           | 6            |             | 12/11/95         | 600 |                   |
| INTRA-ARTICULAR; INJECTION                                |           | 5            |             | 12/31/74         | UNK | 0.71% - 1.0%      |
| INTRABURSAL; INJECTION                                    |           | 4            |             | 02/13/74         | UNK | 0.71%             |
| INTRADERMAL; INJECTION                                    |           | 1            |             |                  |     |                   |
| INTRALESIONAL; INJECTION                                  |           | 2            |             | 12/31/74         | UNK | 0.71% - 1.0%      |
| INTRAMUSCULAR; INJECTION                                  |           | 5            |             | 02/13/74         | 600 | 0.71%             |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION             |           | 2            |             | 10/17/85         | 510 |                   |
| INTRAMUSCULAR; SOLUTION, INJECTION                        |           | 1            |             |                  |     |                   |
| INTRASYNOVIAL; INJECTION, SUSTAINED ACTION                |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                    |           | 10           |             | 11/23/94         | 160 | 0.025% - 1.6%     |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION               |           | 2            |             | 02/07/95         | 180 |                   |
| IV(INFUSION); INJECTION                                   |           | 24           |             | 02/26/93         | 150 | 0.0476% - 1.746%  |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION              |           | 6            |             | 08/31/95         | UNK | 15.8MG            |
| NASAL; SOLUTION   |           | 1            |             |                  |     |                   |
| OPHTHALMIC; SOLUTION                                      |           | 20           |             | 04/28/95         | 600 | 0.07% - 1.21%     |
| OPHTHALMIC; SUSPENSION                                    |           | 10           |             | 11/10/93         | UNK | 0.05% - 0.866%    |
| ORAL; CAPSULE   |           | 2            |             | 08/18/95         | 600 | 35.0MG - 500.0MG  |
| ORAL; SOLUTION  |           | 5            |             | 12/22/94         | 600 | 0.5%              |
| ORAL; SUSPENSION  |           | 4            |             | 12/27/91         | UNK | 0.1% - 0.9%       |
| ORAL; SYRUP   |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 2            |             | 01/17/78         | 600 | 2.1MG - 59.7456MG |
| ORAL; TABLET, COATED                                      |           | 1            |             |                  |     |                   |
| OTIC; SOLUTION  |           | 2            |             | 01/16/85         | 600 | 0.4% - 0.5%       |
| SOFT TISSUE; INJECTION                                    |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; INJECTION                                   |           | 2            |             | 04/25/89         | 510 | 0.2% - 0.378%     |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION              |           | 3            |             | 11/17/93         | 510 |                   |
| SUBCUTANEOUS; SUSPENSION, INJECTION                       |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                                  |           | 3            |             | 12/18/90         | UNK | 0.06% - 1.8%      |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                           | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| SODIUM PHOSPHATE, DIBASIC                                 | 007782856 |              |             |                  |     |                   |
| TOPICAL; LOTION   |           | 3            |             | 10/27/89         | UNK | 0.39% - 1.59%     |
| TOPICAL; SOLUTION   |           | 1            |             |                  |     |                   |
| TOPICAL; SPONGE   |           | 2            |             | 01/01/81         | 500 |                   |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS                      |           |              |             |                  |     |                   |
| IM - IV; POWDER, FOR INJECTION SOLUTION                   |           | 5            |             | 11/30/92         | 600 | 17.5MG - 139.2MG  |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION             |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                    |           | 2            |             | 02/23/76         | 160 | 0.072%            |
| IV(INFUSION); INJECTION                                   |           | 1            |             |                  |     |                   |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION              |           | 3            |             | 03/31/95         | 600 |                   |
| OPHTHALMIC; SOLUTION                                      |           | 3            |             | 07/29/94         | 600 | 0.0397% - 0.426%  |
| OPHTHALMIC; SUSPENSION                                    |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                   |
| ORAL; SYRUP   |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED |           | 1            |             |                  |     |                   |
| TOPICAL; GEL  |           | 1            |             |                  |     |                   |
| SODIUM PHOSPHATE, DIBASIC, DIHYDRATE                      | 010028247 |              |             |                  |     |                   |
| IM - IV; INJECTION  |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                                   |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                     |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                          |           | 1            |             |                  |     |                   |
| SODIUM PHOSPHATE, DRIED                                   |           |              |             |                  |     |                   |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION                    |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                                  |           | 1            |             |                  |     |                   |
| SODIUM PHOSPHATE, MONOBASIC                               | 007558807 |              |             |                  |     |                   |
| IM - IV; INJECTION  |           | 19           |             | 08/29/89         | 600 | 0.5% - 1.2%       |
| IM - IV; POWDER, FOR INJECTION SOLUTION                   |           | 8            |             | 11/30/92         | 600 | 1.6MG - 12.8MG    |
| INTRA-ARTICULAR; INJECTION                                |           | 1            |             |                  |     |                   |
| INTRABURSAL; INJECTION                                    |           | 1            |             |                  |     |                   |
| INTRADERMAL; INJECTION                                    |           | 1            |             |                  |     |                   |
| INTRALESIONAL; INJECTION                                  |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                                  |           | 7            |             | 12/05/88         | 600 | 0.34% - 1.16%     |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION             |           | 3            |             | 10/17/85         | 510 |                   |
| INTRAMUSCULAR; SOLUTION, INJECTION                        |           | 1            |             |                  |     |                   |
| INTRASYNOVIAL; INJECTION, SUSTAINED ACTION                |           | 1            |             |                  |     |                   |
| INTRAVASCULAR; INJECTION                                  |           | 3            |             | 08/29/78         | 160 | 0.0115% - 0.0125% |
| INTRAVENOUS; INJECTION                                    |           | 6            |             | 12/28/90         | 510 | 0.0125% - 0.9%    |
| INTRAVENOUS; SOLUTION                                     |           | 2            |             | 06/17/78         | 160 |                   |
| INTRAVESICAL; SOLUTION                                    |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                                   |           | 13           |             | 08/29/89         | 600 | 0.48% - 0.5%      |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION              |           | 3            |             | 02/27/85         | UNK | 4.4MG             |
| IV(INFUSION); SOLUTION, INJECTION                         |           | 1            |             |                  |     |                   |
| OPHTHALMIC; SOLUTION                                      |           | 20           |             | 04/28/95         | 600 | 0.01% - 0.721%    |
| OPHTHALMIC; SUSPENSION                                    |           | 8            |             | 09/29/89         | UNK | 0.036% - 0.37%    |
| ORAL; CONCENTRATE   |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION  |           | 3            |             | 05/28/86         | UNK |                   |
| ORAL; SUSPENSION  |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                        | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| SODIUM PHOSPHATE, MONOBASIC                            | 007558807 |              |             |                  |     |                   |
| ORAL; SYRUP  |           | 2            |             | 06/19/62         | UNK | 0.07%             |
| ORAL; TABLET   |           | 1            |             |                  |     |                   |
| OTIC; SOLUTION   |           | 1            |             |                  |     |                   |
| SOFT TISSUE; INJECTION, SUSTAINED ACTION               |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; INJECTION                                |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION           |           | 2            |             | 11/17/93         | 510 |                   |
| TOPICAL; EMULSION, CREAM                               |           | 15           |             | 11/20/92         | UNK | 0.01% - 0.45%     |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                   |
| TOPICAL; SUSPENSION, SHAMPOO                           |           | 3            |             | 01/10/91         | 600 | 0.11199%          |
| VAGINAL; EMULSION, CREAM                               |           | 2            |             | 07/16/93         | 600 |                   |
| SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE               | 010049215 |              |             |                  |     |                   |
| IM - IV; INJECTION                                     |           | 3            |             | 07/08/87         | 600 | 1.2%              |
| IM - IV; POWDER, FOR INJECTION SOLUTION                |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION, LYOPHIL |           | 1            |             |                  |     |                   |
| INTRAVASCULAR; INJECTION                               |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                 |           | 3            |             | 11/23/94         | 160 | 0.0125%           |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION            |           | 1            |             |                  |     |                   |
| INTRAVESICAL; SOLUTION                                 |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                                |           | 3            |             | 07/08/87         | 600 | 1.2%              |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION           |           | 2            |             | 03/31/95         | 600 |                   |
| OPHTHALMIC; SOLUTION                                   |           | 5            |             | 10/24/91         | 600 | 0.045% - 0.4%     |
| OPHTHALMIC; SUSPENSION                                 |           | 3            |             | 11/10/93         | UNK | 0.1% - 0.536%     |
| TOPICAL; EMULSION, CREAM                               |           | 3            |             | 07/10/84         | UNK | 0.265%            |
| TOPICAL; LOTION, AUGMENTED                             |           | 1            |             |                  |     |                   |
| URETERAL; SOLUTION                                     |           | 1            |             |                  |     |                   |
| SODIUM PHOSPHATE, TRIBASIC                             | 007601549 |              |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                       |           | 2            |             | 10/19/95         | 520 |                   |
| SODIUM PROPIONATE                                      | 000137406 |              |             |                  |     |                   |
| ORAL; CAPSULE  |           | 34           |             | 12/20/95         | 520 |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                        |           | 4            |             | 02/14/94         | 600 |                   |
| ORAL; POWDER, FOR RECONSTITUTION                       |           | 4            |             | 07/10/80         | 600 | 0.125% - 0.3%     |
| ORAL; SUSPENSION                                       |           | 1            |             |                  |     |                   |
| ORAL; SYRUP  |           | 4            |             | 04/18/84         | UNK | 1.0%              |
| SODIUM PYROPHOSPHATE                                   | 007722885 |              |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                 |           | 2            |             | 10/20/76         | 160 |                   |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION            |           | 1            |             |                  |     |                   |
| SODIUM PYRROLIDONE CARBOXYLATE                         |           |              |             |                  |     |                   |
| TOPICAL; LOTION  |           | 2            |             | 11/26/85         | 600 | 0.4%              |
| SODIUM STARCH GLYCOLATE                                | 009063381 |              |             |                  |     |                   |
| ORAL; CAPLET   |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE  |           | 51           |             | 12/20/95         | 520 | 3.0MG - 134.0MG   |
| ORAL; CAPSULE, COATED PELLETS                          |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, HARD GELATIN                            |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                        |           | 1            |             |                  |     |                   |
| ORAL; TABLET   |           | 702          |             | 12/28/95         | 600 | 0.031MG - 738.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,         |           | 4            |             | 01/04/95         | 600 | 0.06MG - 4.5MG    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| SODIUM STARCH GLYCOLATE                      | 009063381 | 27           |             | 06/23/95         | 600 | 1.2MG - 32.01MG   |
| ORAL; TABLET, COATED                         |           | 3            |             | 02/10/00         | 520 | 10.0MG - 21.0MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED |           | 1            |             |                  |     |                   |
| ORAL; TABLET, ENTERIC COATED PARTICLES       |           | 32           |             | 12/27/95         | 150 | 1.5MG - 53.0MG    |
| ORAL; TABLET, FILM COATED                    |           | 4            |             | 08/19/91         | UNK | 0.75MG - 31.3MG   |
| ORAL; TABLET, SUSTAINED ACTION               |           | 1            |             |                  |     |                   |
| ORAL-21; TABLET                              |           | 4            |             | 05/29/76         | 510 |                   |
| ORAL-28; TABLET                              |           | 5            |             | 02/26/88         | 600 | 0.7MG - 2.0MG     |
| SUBLINGUAL; TABLET                           |           |              |             |                  |     |                   |
| SODIUM STEARYL FUMARATE                      |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE                                |           | 10           |             | 03/28/95         | 110 | 1.8MG - 6.0MG     |
| ORAL; TABLET                                 |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION               |           |              |             |                  |     |                   |
| SODIUM SUCCINATE                             | 000150903 | 1            |             |                  |     |                   |
| ORAL; CONCENTRATE                            |           |              |             |                  |     |                   |
| SODIUM SULFATE                               | 007727733 | 2            |             | 05/25/94         | 600 | 0.04%             |
| OPHTHALMIC; SOLUTION                         |           | 1            |             |                  |     |                   |
| OPHTHALMIC; SUSPENSION                       |           |              |             |                  |     |                   |
| SODIUM SULFATE, ANHYDROUS                    | 007757826 | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                     |           | 2            |             | 12/13/84         | 600 | 0.152%            |
| OPHTHALMIC; SOLUTION                         |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                 |           |              |             |                  |     |                   |
| SODIUM SULFITE                               | 007757837 | 1            |             |                  |     |                   |
| EPIDURAL; INJECTION                          |           | 16           |             | 05/13/88         | 600 | 0.08% - 0.15%     |
| IM - IV; INJECTION                           |           | 6            |             | 09/16/83         | 600 | 0.025%            |
| INHALATION; SOLUTION                         |           | 3            |             | 04/09/86         | 600 | 0.1%              |
| INTRA-ARTICULAR; INJECTION                   |           | 1            |             |                  |     |                   |
| INTRALESIONAL; INJECTION                     |           | 3            |             | 04/15/88         | 600 | 0.05% - 0.1%      |
| INTRAMUSCULAR; INJECTION                     |           | 4            |             | 11/06/91         | UNK | 0.15% - 0.2%      |
| INTRAVENOUS; INJECTION                       |           | 2            |             | 07/08/87         | 600 | 0.1%              |
| IV(INFUSION); INJECTION                      |           | 3            |             | 04/27/83         | 600 | 0.015% - 0.04993% |
| ORAL; CONCENTRATE                            |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                             |           | 1            |             |                  |     |                   |
| OTIC; SOLUTION                               |           | 1            |             |                  |     |                   |
| SOFT TISSUE; INJECTION                       |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                     |           | 1            |             |                  |     |                   |
| SODIUM TARTRATE                              | 000868188 | 4            |             | 08/29/89         | 600 | 1.2%              |
| IM - IV; INJECTION                           |           | 4            |             | 12/05/88         | 600 | 0.475% - 1.2%     |
| INTRAMUSCULAR; INJECTION                     |           | 2            |             | 06/15/90         | 160 |                   |
| INTRAVENOUS; INJECTION                       |           | 4            |             | 08/29/89         | 600 | 1.2%              |
| IV(INFUSION); INJECTION                      |           |              |             |                  |     |                   |
| SODIUM THIOGLYCOLATE                         | 000367511 | 1            |             |                  |     |                   |
| SUBCUTANEOUS; INJECTION                      |           |              |             |                  |     |                   |
| SODIUM THIOSULFATE                           | 010102177 | 1            |             |                  |     |                   |
| INTRAVENOUS; SOLUTION                        |           | 9            |             | 05/05/87         | 600 | 0.0902% - 0.31%   |
| OPHTHALMIC; SOLUTION                         |           | 6            |             | 09/29/89         | UNK | 0.1% - 0.32%      |
| OPHTHALMIC; SUSPENSION                       |           |              |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE    |
|--|-----------|--------------|-------------|------------------|-----|------------------|
| SODIUM THIOSULFATE                             | 010102177 | 1            |             |                  |     |                  |
| ORAL; CAPSULE                                  |           | 4            |             | 08/18/78         | 160 | 0.248%           |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                  |
| SODIUM THIOSULFATE, ANHYDROUS                  | 007772987 | 3            |             | 04/17/78         | 160 |                  |
| INTRAVENOUS; SOLUTION                          |           | 4            |             | 04/17/78         | 160 | 0.2%             |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                  |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                  |
| SODIUM TRIMETAPHOSPHATE                        | 007785844 | 1            |             |                  |     |                  |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION    |           | 1            |             |                  |     |                  |
| SOLULAN  | 008042511 | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, AEROSOL FOAM                |           | 1            |             |                  |     |                  |
| TOPICAL; SOLUTION                              |           | 1            |             |                  |     |                  |
| SORBIC ACID                                    | 000110441 | 1            |             |                  |     |                  |
| OPHTHALMIC; SOLUTION                           |           | 1            |             |                  |     |                  |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                  |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                  |
| ORAL; SUSPENSION                               |           | 4            |             | 10/10/85         | UNK | 0.1% - 0.116%    |
| ORAL; SYRUP                                    |           | 7            |             | 12/23/88         | 600 | 0.1%             |
| ORAL; TABLET                                   |           | 11           |             | 11/05/92         | 600 | 0.01MG - 0.55MG  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                  |
| ORAL; TABLET, COATED                           |           | 3            |             | 04/08/81         | UNK |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                  |
| SUBLINGUAL; TABLET                             |           | 2            |             | 04/16/81         | 600 | 0.16MG           |
| TOPICAL; EMULSION, CREAM                       |           | 49           |             | 05/31/91         | 600 | 0.05% - 0.2%     |
| TOPICAL; LOTION                                |           | 7            |             | 11/30/82         | 600 | 0.1% - 0.2%      |
| TOPICAL; OINTMENT                              |           | 3            |             | 10/10/85         | 600 | 0.1%             |
| SORBITAN MONOLAURATE                           | 005959897 | 1            |             |                  |     |                  |
| OPHTHALMIC; OINTMENT                           |           | 1            |             |                  |     |                  |
| ORAL; GRANULE, EFFERVESCENT                    |           | 3            |             | 11/21/80         | 600 |                  |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                  |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                  |
| SORBITAN MONOOLEATE                            | 005938385 | 2            |             | 10/31/91         | 520 | 1.0MG            |
| ORAL; TABLET                                   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                  |
| ORAL; TABLET, FILM COATED                      |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM                       |           | 11           |             | 07/11/90         | 520 | 0.25% - 2.5%     |
| TOPICAL; LOTION                                |           | 2            |             | 12/07/92         | UNK | 7.0%             |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                  |
| SORBITAN MONOPALMITATE                         | 001338405 | 2            |             | 12/23/75         | 520 | 0.05%            |
| INTRAMUSCULAR; INJECTION                       |           | 1            |             |                  |     |                  |
| TOPICAL; EMULSION, CREAM                       |           | 6            |             | 08/14/86         | 600 | 0.08005% - 0.45% |
| TOPICAL; LOTION                                |           | 6            |             |                  |     |                  |
| SORBITAN MONOSTEARATE                          | 001338416 | 54           |             | 06/13/95         | 600 | 0.25% - 5.2%     |
| TOPICAL; EMULSION, CREAM                       |           | 6            |             | 01/24/92         | 600 | 0.14% - 2.5%     |
| TOPICAL; LOTION                                |           | 6            |             |                  |     |                  |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                  |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM   | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|-----------------------------------|-----------|--------------|-------------|------------------|-----|-------------------|
| SORBITAN MONOSTEARATE             | 001338416 | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION                 |           | 1            |             |                  |     |                   |
| TOPICAL; SUPPOSITORY              |           | 7            |             | 12/21/95         | 520 | 2.0%              |
| VAGINAL; EMULSION, CREAM          |           | 1            |             |                  |     |                   |
| VAGINAL; SUPPOSITORY              |           |              |             |                  |     |                   |
| SORBITAN SESQUIOLEATE             | 008007430 | 14           |             | 03/31/95         | 600 | 0.5% - 2.0%       |
| TOPICAL; OINTMENT                 |           |              |             |                  |     |                   |
| SORBITAN SOLUTION                 |           | 1            |             |                  |     |                   |
| ORAL; CONCENTRATE                 |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                  |           |              |             |                  |     |                   |
| SORBITAN TRIOLEATE                | 005960065 | 12           |             | 12/30/92         | UNK | 0.5%              |
| INHALATION; AEROSOL, METERED      |           | 1            |             |                  |     |                   |
| NASAL; AEROSOL, METERED           |           | 1            |             |                  |     |                   |
| ORAL; TABLET                      |           |              |             |                  |     |                   |
| SORBITOL                          | 000050704 | 2            |             | 06/08/92         | UNK |                   |
| BUCCAL; GUM, CHEWING              |           | 2            |             | 02/17/84         | 600 | 45.0%             |
| INTRA-ARTICULAR; INJECTION        |           | 2            |             | 07/17/84         | 400 | 45.0%             |
| INTRALESIONAL; INJECTION          |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION          |           | 2            |             | 02/11/84         | 600 | 45.0%             |
| INTRASYNOVIAL; INJECTION          |           | 2            |             | 08/18/85         | 110 | 4.8% - 7.14%      |
| INTRAVENOUS; INJECTION            |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION           |           | 2            |             | 05/18/70         | 510 | 2.5%              |
| NASAL; SOLUTION                   |           | 1            |             |                  |     |                   |
| NASAL; SPRAY, METERED             |           | 9            |             | 07/30/93         | 600 | 51.1MG - 71.22MG  |
| ORAL; CAPSULE                     |           | 4            |             | 03/08/94         | 180 | 66.82MG           |
| ORAL; CAPSULE, SOFT GELATIN       |           | 8            |             | 01/30/92         | 400 | 30.0% - 60.0%     |
| ORAL; CONCENTRATE                 |           | 1            |             |                  |     |                   |
| ORAL; GRANULE, FOR RECONSTITUTION |           | 9            |             | 10/31/93         | 600 | 35.0%             |
| ORAL; SOLUTION                    |           | 2            |             | 04/23/64         | UNK |                   |
| ORAL; SOLUTION, ELIXIR            |           | 8            |             | 02/12/86         | 520 | 70.0%             |
| ORAL; SUSPENSION                  |           | 18           |             | 09/17/93         | 530 | 5.0% - 72.0%      |
| ORAL; SYRUP                       |           | 7            |             | 11/01/85         | 600 | 0.004GM - 0.016GM |
| ORAL; TABLET                      |           | 3            |             | 03/15/62         | 120 | 6.48MG            |
| ORAL; TABLET, COATED              |           | 2            |             | 08/10/82         | 520 | 2.5MG - 5.0MG     |
| ORAL; TABLET, FILM COATED         |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION    |           | 2            |             |                  |     |                   |
| RECTAL; SUSPENSION                |           | 1            |             |                  |     |                   |
| SUBLINGUAL; TABLET                |           | 8            |             | 08/11/81         | 600 |                   |
| TOPICAL; EMULSION, CREAM          |           | 1            |             | 04/29/94         | 600 | 2.377% - 5.0%     |
| TOPICAL; LOTION                   |           | 1            |             |                  |     |                   |
| VAGINAL; TABLET                   |           |              |             |                  |     |                   |
| SORBITOL SOLUTION                 | 003959533 | 1            |             |                  |     |                   |
| INTRA-ARTICULAR; INJECTION        |           | 1            |             |                  |     |                   |
| INTRALESIONAL; INJECTION          |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION          |           | 1            |             |                  |     |                   |
| NASAL; SPRAY, METERED             |           | 1            |             |                  |     |                   |
| ORAL; CONCENTRATE                 |           | 5            |             | 07/20/88         | 600 | 5.0% - 30.0%      |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                        | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| SORBITOL SOLUTION                                      | 003959533 |              |             |                  |     |                    |
| ORAL; DROPS  |           | 1            |             |                  |     |                    |
| ORAL; SOLUTION   |           | 28           |             | 12/22/94         | 600 | 20.0% - 90.0%      |
| ORAL; SOLUTION, ELIXIR                                 |           | 9            |             | 10/27/92         | 600 | 2.5%               |
| ORAL; SUSPENSION                                       |           | 18           |             | 09/15/95         | 180 | 12.86% - 38.55%    |
| ORAL; SYRUP  |           | 45           |             | 07/17/95         | 600 | 0.01% - 66.0%      |
| RECTAL; SUSPENSION                                     |           | 2            |             | 11/17/84         | 600 |                    |
| TOPICAL; CREAM, AUGMENTED                              |           | 1            |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                               |           | 31           |             | 09/20/95         | UNK | 0.3% - 25.0%       |
| TOPICAL; LOTION  |           | 2            |             | 12/07/92         | UNK | 4.0% - 5.0%        |
| TOPICAL; OINTMENT                                      |           | 5            |             | 10/10/85         | 600 | 1.5%               |
| SOYBEAN OIL  | 008001227 |              |             |                  |     |                    |
| INTRAVENOUS; EMULSION, INJECTION                       |           | 1            |             |                  |     |                    |
| INTRAVENOUS; INJECTION                                 |           | 1            |             |                  |     |                    |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION, LYOPHILI |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE  |           | 5            |             | 09/04/86         | 600 | 60.25MG - 230.0MG  |
| ORAL; CAPSULE, SOFT GELATIN                            |           | 3            |             | 11/22/95         | 150 | 103.0MG - 216.84MG |
| SOYBEAN OIL, HYDROGENATED                              | 008016704 |              |             |                  |     |                    |
| ORAL; CAPSULE  |           | 2            |             | 09/04/86         | 600 | 1.0MG              |
| ORAL; CAPSULE, SOFT GELATIN                            |           | 2            |             | 11/22/95         | 150 | 7.579MG - 15.16MG  |
| ORAL; TABLET, COATED                                   |           | 1            |             |                  |     | 3.0MG              |
| SPEARMINT OIL  | 008008795 |              |             |                  |     |                    |
| ORAL; SOLUTION   |           | 1            |             |                  |     |                    |
| ORAL; SYRUP  |           | 3            |             | 04/12/82         | 600 | 0.002%             |
| TOPICAL; OINTMENT                                      |           | 1            |             |                  |     |                    |
| SPECTRABLEND CSL-15764 (BLUE)                          |           |              |             |                  |     |                    |
| ORAL; TABLET   |           | 1            |             |                  |     |                    |
| SPERMACETI   | 008002231 |              |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                               |           | 8            |             | 11/30/77         | 600 | 0.7% - 11.0%       |
| SQUALANE   | 000111013 |              |             |                  |     |                    |
| TOPICAL; EMULSION, CREAM                               |           | 2            |             | 08/16/74         | 600 | 2.0%               |
| STANNOUS CHLORIDE                                      | 010025691 |              |             |                  |     |                    |
| INTRAVENOUS; INJECTION                                 |           | 18           |             | 12/21/90         | 160 | 0.0006%            |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION            |           | 4            |             | 03/25/83         | 160 |                    |
| IV(INFUSION); INJECTION                                |           | 2            |             | 06/10/91         | 160 |                    |
| STANNOUS CHLORIDE, ANHYDROUS                           | 007772998 |              |             |                  |     |                    |
| INTRAVENOUS; INJECTION                                 |           | 2            |             | 12/19/90         | 160 |                    |
| IV(INFUSION); INJECTION                                |           | 1            |             |                  |     |                    |
| STANNOUS FLUORIDE                                      | 007783473 |              |             |                  |     |                    |
| INTRAVENOUS; INJECTION                                 |           | 3            |             | 01/21/87         | 160 |                    |
| STANNOUS TARTRATE                                      | 000815850 |              |             |                  |     |                    |
| INTRAVENOUS; INJECTION                                 |           | 1            |             |                  |     |                    |
| STARCH   | 009005258 |              |             |                  |     |                    |
| BUCCAL/SUBLINGUAL; TABLET                              |           | 1            |             |                  |     |                    |
| INTRAMUSCULAR; INJECTION                               |           | 1            |             |                  |     |                    |
| ORAL; CAPLET   |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE  |           | 98           |             | 07/03/95         | 600 | 2.65%              |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| STARCH   | 009005258 |              |             |                  |     |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 27           |             | 02/08/95         | UNK | 0.64MG - 120.0MG  |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                   |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                   |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 571          |             | 11/22/95         | 600 | 0.023MG - 257.6MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 3            |             | 06/28/89         | 600 | 25.75MG - 170.0MG |
| ORAL; TABLET, COATED                           |           | 34           |             | 06/23/95         | 600 | 4.0MG - 209.0MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 3            |             | 07/28/88         | UNK | 20.0MG - 58.0MG   |
| ORAL; TABLET, DISPERSIBLE                      |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                      |           | 29           |             | 03/14/95         | 600 | 2.0MG - 88.0MG    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 4            |             | 08/21/92         | UNK | 0.21MG - 32.0MG   |
| ORAL-21; TABLET                                |           | 9            |             | 02/09/89         | 600 | 6.2MG - 11.125MG  |
| ORAL-28; TABLET                                |           | 10           |             | 02/09/89         | 600 | 1.0MG - 10.0MG    |
| SUBLINGUAL; TABLET                             |           | 4            |             | 07/29/88         | 110 | 3.0MG - 28.611MG  |
| VAGINAL; TABLET                                |           | 3            |             | 11/09/83         | 600 | 25.0MG - 57.5MG   |
| STARCH 1500, PREGELATINIZED                    |           |              |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 4            |             | 10/03/86         | 600 | 20.0MG - 143.0MG  |
| ORAL; TABLET                                   |           | 97           |             | 10/05/95         | 600 | 1.5MG - 333.0MG   |
| ORAL; TABLET, COATED                           |           | 5            |             | 09/10/87         | 600 | 9.2MG - 22.0MG    |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 04/28/95         | 600 | 59.5MG - 78.4MG   |
| STARCH 1551                                    |           |              |             |                  |     |                   |
| ORAL; TABLET                                   |           | 9            |             | 08/08/88         | 600 | 4.0MG - 33.75MG   |
| STARCH, CORN                                   |           |              |             |                  |     |                   |
| BUCCAL; TABLET                                 |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE                                  |           | 197          |             | 12/29/95         | 600 | 0.152GM           |
| ORAL; CAPSULE, HARD GELATIN                    |           | 2            |             | 03/27/95         | 600 | 10.0MG - 289.2MG  |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 5            |             | 01/26/89         | 600 |                   |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                   |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                   |
| ORAL; PASTILLE                                 |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 06/20/88         | UNK |                   |
| ORAL; SUSPENSION                               |           | 1            |             |                  |     |                   |
| ORAL; TABLET                                   |           | 490          |             | 11/30/95         | 600 | 0.055GM           |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 5            |             | 01/04/95         | 600 | 50.0MG - 117.0MG  |
| ORAL; TABLET, COATED                           |           | 35           |             | 02/28/95         | 600 | 0.63MG - 285.0MG  |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 2            |             | 06/06/88         | UNK | 40.6MG - 94.48MG  |
| ORAL; TABLET, DISPERSIBLE                      |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                      |           | 26           |             | 12/08/95         | UNK | 5.6MG - 88.0MG    |
| ORAL; TABLET, REPEAT ACTION                    |           | 2            |             | 03/31/81         | UNK | 20.0MG - 30.0MG   |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 11           |             | 01/04/95         | 600 | 14.66MG - 187.5MG |
| ORAL-21; TABLET                                |           | 4            |             | 12/14/92         | 510 | 24.6MG            |
| ORAL-28; TABLET                                |           | 10           |             | 12/13/93         | 600 | 6.5MG - 30.1MG    |
| SUBLINGUAL; TABLET                             |           | 4            |             | 06/08/84         | 600 | 3.2MG - 50.6MG    |
| VAGINAL; TABLET                                |           | 5            |             | 12/26/91         | 520 | 50.0MG - 150.0MG  |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-------|--------------|-------------|------------------|-----|--------------------|
| STARCH, POTATO                                 |       | 17           |             | 09/06/95         | 510 | 12.0MG - 77.0MG    |
| ORAL; TABLET                                   |       | 6            |             | 02/25/92         | 600 | 11.88MG - 13.26MG  |
| ORAL; TABLET, COATED                           |       | 1            |             |                  |     |                    |
| ORAL; TABLET, REPEAT ACTION                    |       |              |             |                  |     |                    |
| STARCH, PREGELATINIZED                         |       | 1            |             |                  |     |                    |
| ORAL; CAPLET                                   |       | 79           |             | 10/18/95         | 600 | 2.7MG - 360.0MG    |
| ORAL; CAPSULE                                  |       | 4            |             | 05/03/95         | 530 | 41.9MG - 81.0MG    |
| ORAL; CAPSULE, HARD GELATIN                    |       | 2            |             | 05/29/92         | 110 | 82.03MG - 141.75MG |
| ORAL; CAPSULE, SUSTAINED ACTION                |       | 1            |             |                  |     | 1.2%               |
| ORAL; DROPS                                    |       | 1            |             |                  |     |                    |
| ORAL; SUSPENSION                               |       | 1            |             |                  |     |                    |
| ORAL; SUSPENSION, SUSTAINED ACTION             |       | 1            |             |                  |     |                    |
| ORAL; TABLET                                   |       | 378          |             | 12/29/95         | 600 | 0.005MG - 435.0MG  |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 1            |             |                  |     |                    |
| ORAL; TABLET, COATED                           |       | 1            |             |                  |     |                    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |       | 2            |             | 06/29/95         | 600 | 15.0MG - 45.0MG    |
| ORAL; TABLET, DISPERSIBLE                      |       | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                      |       | 21           |             | 09/29/95         | 600 | 10.0MG - 141.0MG   |
| ORAL; TABLET, SUSTAINED ACTION, COATED         |       | 1            |             |                  |     |                    |
| ORAL-21; TABLET                                |       | 9            |             | 07/03/92         | 510 | 10.0MG - 22.25MG   |
| ORAL-28; TABLET                                |       | 9            |             | 07/03/92         | 510 | 10.0MG - 22.5MG    |
| SUBLINGUAL; TABLET                             |       | 5            |             | 08/11/81         | 600 | 12.0MG - 43.0MG    |
| STARCH, PREGELATINIZED CORN                    |       | 11           |             | 06/28/91         | 600 | 50.0MG - 161.1MG   |
| ORAL; CAPSULE                                  |       | 74           |             | 12/29/95         | 600 | 1.8MG - 482.0MG    |
| ORAL; TABLET                                   |       | 1            |             |                  |     |                    |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |       | 1            |             |                  |     |                    |
| ORAL; TABLET, COATED                           |       | 1            |             |                  |     |                    |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |       | 2            |             | 11/25/88         | 600 |                    |
| ORAL; TABLET, FILM COATED                      |       | 5            |             | 12/31/92         | 180 | 6.25MG - 12.5MG    |
| STARCH, PREGELATINIZED TAPIOCA                 |       |              |             |                  |     |                    |
| ORAL; TABLET                                   |       | 1            |             |                  |     |                    |
| STARCH, RICE                                   |       |              |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION                 |       | 1            |             |                  |     |                    |
| STARCH, TAPIOCA                                |       |              |             |                  |     |                    |
| ORAL; TABLET                                   |       | 1            |             |                  |     |                    |
| STARCH, WHEAT                                  |       |              |             |                  |     |                    |
| ORAL; CAPSULE, SUSTAINED ACTION                |       | 3            |             | 01/04/95         | 600 | 0.25MG - 0.75MG    |
| ORAL; TABLET                                   |       | 1            |             |                  |     |                    |
| ORAL; TABLET, COATED                           |       | 1            |             |                  |     |                    |
| STEAR-O-WET C                                  |       |              |             |                  |     |                    |
| ORAL; TABLET                                   |       | 4            |             | 08/31/94         | 600 | 6.0MG - 12.0MG     |
| STEAR-O-WET H                                  |       |              |             |                  |     |                    |
| ORAL; CAPSULE                                  |       | 10           |             | 12/28/90         | 600 | 0.65MG - 14.0MG    |
| ORAL; TABLET                                   |       | 32           |             | 05/17/94         | 600 | 0.03MG - 31.5MG    |
| ORAL; TABLET, FILM COATED                      |       | 3            |             | 02/16/95         | 600 | 0.75MG - 8.0MG     |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE        |
|--|-----------|--------------|-------------|------------------|-----|----------------------|
| STEARALKONIUM CHLORIDE<br>TOPICAL; LOTION  | 000122190 | 1            |             |                  |     |                      |
| STEARALKONIUM HECTORITE/PROPYLENE CARBONATE<br>TRANSDERMAL; FILM, CONTROLLED RELEASE |           | 1            |             |                  |     |                      |
| STEARAMIDOETHYL DIETHYLAMINE<br>TOPICAL; EMULSION, CREAM                             |           | 1            |             |                  |     |                      |
| VAGINAL; EMULSION, CREAM   |           | 4            |             | 06/09/86         | 600 | 0.5% - 0.8%          |
| STEARETH<br>ORAL; TABLET   | 009005009 | 1            |             |                  |     |                      |
| TOPICAL; EMULSION, CREAM   |           | 1            |             |                  |     |                      |
| TOPICAL; OINTMENT  |           | 1            |             |                  |     |                      |
| STEARETH-10<br>RECTAL; EMULSION, AEROSOL FOAM  |           | 1            |             |                  |     |                      |
| TOPICAL; EMULSION, AEROSOL FOAM  |           | 1            |             |                  |     |                      |
| STEARETH-100<br>TOPICAL; OINTMENT  |           | 1            |             |                  |     |                      |
| STEARETH-2<br>TOPICAL; EMULSION, CREAM   |           | 2            |             | 09/04/92         | UNK | 2.75%                |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                      |
| TOPICAL; OINTMENT  |           | 2            |             | 12/29/93         | UNK | 2.5% - 5.0%          |
| STEARETH-21<br>TOPICAL; EMULSION, CREAM  |           | 2            |             | 09/04/92         | UNK | 2.25% - 3.0%         |
| STEARIC ACID<br>IMPLANTATION; PELLET   | 000057114 | 1            |             |                  |     |                      |
| ORAL; CAPLET   |           | 1            |             |                  |     |                      |
| ORAL; CAPSULE  |           | 49           |             | 10/18/95         | 600 | 0.045%               |
| ORAL; CAPSULE, SUSTAINED ACTION  |           | 4            |             | 05/10/93         | 180 | 0.8777MG - 2.367MG   |
| ORAL; POWDER, FOR RECONSTITUTION   |           | 1            |             |                  |     |                      |
| ORAL; SYRUP  |           | 1            |             |                  |     |                      |
| ORAL; TABLET   |           | 586          |             | 11/22/95         | 600 | 0.001385GM - 0.006GM |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,                                       |           | 4            |             | 01/04/95         | 600 | 2.0MG - 15.0MG       |
| ORAL; TABLET, COATED   |           | 29           |             | 09/10/87         | 600 | 0.6MG - 42.4MG       |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 5            |             | 06/29/95         | 600 | 2.0MG - 6.3MG        |
| ORAL; TABLET, DISPERSIBLE  |           | 2            |             | 06/29/95         | 600 |                      |
| ORAL; TABLET, ENTERIC COATED PARTICLES   |           | 1            |             |                  |     |                      |
| ORAL; TABLET, FILM COATED  |           | 23           |             | 10/31/91         | 180 | 0.975MG - 18.0MG     |
| ORAL; TABLET, SUSTAINED ACTION   |           | 16           |             | 04/28/95         | 600 | 1.17MG - 150.0MG     |
| ORAL-21; TABLET  |           | 1            |             |                  |     |                      |
| ORAL-28; TABLET  |           | 4            |             | 11/11/95         | 510 | 0.005MG - 0.65MG     |
| SUBLINGUAL; TABLET   |           | 4            |             | 04/16/81         | 600 | 0.8MG - 5.049MG      |
| TOPICAL; EMULSION, CREAM   |           | 27           |             | 04/29/94         | 600 | 1.2% - 22.5%         |
| TOPICAL; LOTION  |           | 12           |             | 12/07/92         | UNK | 0.0056% - 2.0%       |
| TOPICAL; OINTMENT  |           | 3            |             | 12/23/83         | 600 | 3.0%                 |
| TOPICAL; SOLUTION  |           | 1            |             |                  |     |                      |
| VAGINAL; EMULSION, CREAM   |           | 9            |             | 08/11/92         | 520 | 1.0% - 14.0%         |
| VAGINAL; TABLET  |           | 3            |             | 10/17/85         | 600 | 12.0MG - 32.0MG      |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE      |
|--|-----------|--------------|-------------|------------------|-----|--------------------|
| STEARYL ALCOHOL                                | 000112925 | 1            |             |                  |     |                    |
| ORAL; TABLET, CONTROLLED RELEASE               |           | 2            |             |                  |     |                    |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 60           |             | 09/09/87         | 600 | 244.0MG            |
| TOPICAL; EMULSION, CREAM                       |           | 17           |             | 06/13/95         | 600 | 1.0% - 30.0%       |
| TOPICAL; LOTION                                |           | 4            |             | 09/30/92         | UNK | 0.2% - 4.0%        |
| TOPICAL; OINTMENT                              |           | 5            |             | 08/08/83         | UNK | 0.00075% - 8.0%    |
| VAGINAL; EMULSION, CREAM                       |           |              |             | 12/21/95         | 520 | 6.0% - 7.0%        |
| STEARYL CITRATE                                | 001337333 | 1            |             |                  |     |                    |
| TOPICAL; OINTMENT                              |           |              |             |                  |     |                    |
| SUCCIMER                                       | 000304552 | 1            |             |                  |     |                    |
| INTRAVENOUS; INJECTION                         |           |              |             |                  |     |                    |
| SUCCINIC ACID                                  | 000110156 | 1            |             |                  |     |                    |
| INTRAVENOUS; INJECTION                         |           | 2            |             | 10/31/93         | 600 | 0.2%               |
| ORAL; CONCENTRATE                              |           | 1            |             |                  |     |                    |
| ORAL; POWDER, FOR RECONSTITUTION               |           |              |             |                  |     |                    |
| SUCROSE  | 000057501 | 1            |             |                  |     |                    |
| BUCCAL/SUBLINGUAL; TABLET                      |           | 1            |             |                  |     |                    |
| INTRAVENOUS; SUSPENSION, INJECTION             |           | 22           |             | 09/11/92         | 530 | 5.0MG - 413.655MG  |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                    |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 56           |             | 02/08/95         | UNK | 0.002MG - 236.1MG  |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 9            |             | 11/30/94         | 600 | 10.0% - 71.94%     |
| ORAL; CONCENTRATE                              |           | 3            |             | 05/25/95         | UNK | 30.0%              |
| ORAL; DROPS                                    |           | 7            |             | 04/15/88         | UNK |                    |
| ORAL; GRANULE                                  |           | 1            |             |                  |     |                    |
| ORAL; GRANULE FOR RECONSTITUTION, CR           |           | 2            |             | 12/23/93         | 520 |                    |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                    |
| ORAL; PASTILLE                                 |           | 2            |             |                  |     |                    |
| ORAL; POWDER                                   |           | 61           |             | 12/05/88         | 510 | 0.006368%          |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 13           |             | 12/20/95         | 520 |                    |
| ORAL; SOLUTION                                 |           | 20           |             | 11/17/95         | 530 | 20.0% - 60.0%      |
| ORAL; SOLUTION, ELIXIR                         |           | 42           |             | 04/29/93         | 600 | 12.5% - 29.75%     |
| ORAL; SUSPENSION                               |           | 1            |             | 04/14/95         | UNK | 25.5% - 60.0%      |
| ORAL; SUSPENSION, SUSTAINED ACTION             |           | 49           |             | 10/28/94         | 600 | 23.9659% - 82.105% |
| ORAL; SYRUP                                    |           | 159          |             | 10/06/95         | UNK | 0.0325GM - 0.9GM   |
| ORAL; TABLET                                   |           | 7            |             | 09/11/95         | 600 | 1.2GM - 2.4GM      |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 58           |             | 02/25/92         | 600 | 2.0MG - 300.0MG    |
| ORAL; TABLET, COATED                           |           | 2            |             | 04/23/81         | 600 | 4.99MG             |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 1            |             |                  |     |                    |
| ORAL; TABLET, FILM COATED                      |           | 2            |             |                  |     |                    |
| ORAL; TABLET, REPEAT ACTION                    |           | 14           |             | 03/31/81         | UNK | 129.551MG          |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             | 01/04/95         | 600 | 63.9MG - 202.0MG   |
| ORAL; TABLET, UNCOATED, TROCHE                 |           | 1            |             |                  |     |                    |
| ORAL-21; TABLET                                |           | 1            |             |                  |     |                    |
| ORAL-28; TABLET                                |           | 7            |             |                  |     |                    |
| RECTAL; SOLUTION                               |           | 1            |             |                  |     |                    |
| SUBLINGUAL; TABLET                             |           | 1            |             |                  |     |                    |
| TOPICAL; OINTMENT                              |           | 1            |             |                  |     |                    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                           | CAS # | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE        |
|---|-------|--------------|-------------|------------------|-----|----------------------|
| SUCROSE POLYESTERS<br>TOPICAL; POWDER, FOR RECONSTITUTION |       | 1            |             |                  |     |                      |
| SUCROSE STEARATE<br>ORAL; CAPSULE, SUSTAINED ACTION       |       | 1            |             |                  |     |                      |
| SUCROSE SYRUP<br>ORAL; SOLUTION                           |       | 2            |             | 04/27/88         | 510 |                      |
| ORAL; SUSPENSION  |       | 1            |             |                  |     |                      |
| ORAL; SYRUP   |       | 3            |             | 01/13/95         | 600 |                      |
| ORAL; TABLET  |       | 1            |             |                  |     |                      |
| SUGAR COMPRESSIBLE<br>ORAL; CAPSULE                       |       | 3            |             | 05/16/89         | 600 | 150.0MG - 270.0MG    |
| ORAL; TABLET  |       | 2            |             | 01/16/84         | 600 |                      |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,            |       | 2            |             | 06/28/89         | 600 | 258.0MG - 623.5MG    |
| SUGAR CONFECTIONERS<br>ORAL; CAPSULE                      |       | 3            |             | 05/16/89         | 600 | 319.81MG - 527.425MG |
| ORAL; CAPSULE, HARD GELATIN                               |       | 1            |             |                  |     |                      |
| ORAL; CAPSULE, SUSTAINED ACTION                           |       | 1            |             |                  |     |                      |
| ORAL; TABLET  |       | 25           |             | 04/16/91         | 600 | 2.28MG - 90.0MG      |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,            |       | 3            |             | 06/28/89         | 600 | 555.0MG - 737.5MG    |
| ORAL; TABLET, COATED                                      |       | 7            |             | 09/10/87         | 600 | 10.0MG - 54.0MG      |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED              |       | 1            |             |                  |     |                      |
| ORAL; TABLET, SUSTAINED ACTION                            |       | 6            |             | 01/04/95         | 600 | 117.0MG - 175.0MG    |
| ORAL-21; TABLET   |       | 2            |             | 10/01/76         | 510 |                      |
| ORAL-28; TABLET   |       | 2            |             | 04/30/73         | 510 |                      |
| SUGAR FRUIT FINE<br>ORAL; POWDER, FOR RECONSTITUTION      |       | 2            |             | 02/13/87         | 600 | 24.74% - 27.48%      |
| ORAL; TABLET  |       | 2            |             | 01/10/86         | 600 | 31.154MG - 43.8MG    |
| SUGAR LIQUID TYPE #0<br>ORAL; SYRUP                       |       | 4            |             | 01/04/85         | 600 |                      |
| SUGAR NON-PAREIL SEEDS<br>ORAL; CAPSULE                   |       | 2            |             | 01/30/91         | 180 | 314.57MG - 388.5MG   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                     |       | 1            |             |                  |     |                      |
| ORAL; CAPSULE, SUSTAINED ACTION                           |       | 2            |             | 01/09/92         | 110 | 30.0MG - 60.0MG      |
| ORAL; TABLET  |       | 1            |             |                  |     | MG                   |
| SUGAR/STARCH INSERT GRANULES<br>ORAL; SOLUTION, ELIXIR    |       | 1            |             |                  |     |                      |
| ORAL; SUSPENSION  |       | 1            |             |                  |     |                      |
| SUGARS (UNIDENTIFIED)<br>ORAL; CAPSULE, COATED PELLETS    |       | 1            |             |                  |     |                      |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                     |       | 1            |             |                  |     |                      |
| ORAL; CAPSULE, SUSTAINED ACTION                           |       | 1            |             |                  |     |                      |
| ORAL; CONCENTRATE   |       | 1            |             |                  |     |                      |
| ORAL; POWDER, FOR RECONSTITUTION                          |       | 3            |             | 10/10/73         | 600 |                      |
| ORAL; SOLUTION  |       | 5            |             | 08/25/92         | 600 | 6.0%                 |
| ORAL; SOLUTION, ELIXIR                                    |       | 1            |             |                  |     |                      |
| ORAL; SUSPENSION  |       | 1            |             |                  |     |                      |
| ORAL; SYRUP   |       | 6            |             | 09/28/89         | 530 |                      |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| SUGARS (UNIDENTIFIED)                          |           |              |             |                  |     |                     |
| ORAL; TABLET                                   |           | 7            |             | 11/24/93         | UNK | 19.544MG - 97.244MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 12/31/80         | 600 | 96.65MG - 1438.0MG  |
| RECTAL; SOLUTION                               |           | 2            |             | 08/25/92         | 600 | 6.0%                |
| SULFURIC ACID                                  | 007664939 |              |             |                  |     |                     |
| EPIDURAL; INJECTION                            |           | 4            |             | 09/30/91         | 600 |                     |
| IM - IV; INJECTION                             |           | 35           |             | 12/14/95         | 600 |                     |
| INHALATION; SOLUTION                           |           | 7            |             | 09/26/95         | 600 |                     |
| INTRAMUSCULAR; INJECTION                       |           | 10           |             | 06/26/95         | 600 |                     |
| INTRAMUSCULAR; SOLUTION, INJECTION             |           | 1            |             |                  |     |                     |
| INTRAPERITONEAL; INJECTION                     |           | 1            |             |                  |     |                     |
| INTRATHECAL; INJECTION                         |           | 4            |             | 09/30/91         | 600 |                     |
| INTRAVENOUS; INJECTION                         |           | 16           |             | 06/26/95         | 600 |                     |
| INTRAVENOUS; SOLUTION, INJECTION               |           | 1            |             |                  |     |                     |
| IV(INFUSION); INJECTION                        |           | 17           |             | 06/26/95         | 600 |                     |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION   |           | 1            |             |                  |     |                     |
| IV(INFUSION); SOLUTION, INJECTION              |           | 1            |             |                  |     |                     |
| OPHTHALMIC; SOLUTION                           |           | 5            |             | 05/25/94         | 600 |                     |
| OPHTHALMIC; SUSPENSION                         |           | 3            |             | 08/18/88         | UNK |                     |
| OTIC; SUSPENSION                               |           | 2            |             | 09/29/87         | 600 |                     |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                     |
| SULFUROUS ACID                                 | 007782992 |              |             |                  |     |                     |
| INTRAMUSCULAR; INJECTION                       |           | 1            |             |                  |     |                     |
| SUPPOCIRE                                      | 008043150 |              |             |                  |     |                     |
| VAGINAL; SUPPOSITORY                           |           | 1            |             |                  |     |                     |
| SYNCHRON ORAL CARRIER                          |           |              |             |                  |     |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 3            |             | 02/21/85         | 600 | 184.3MG - 475.0MG   |
| SYNCHRON ORAL CARRIER VEHICLE TYPE EM          |           |              |             |                  |     |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 1            |             |                  |     |                     |
| TAGATOSE                                       |           |              |             |                  |     |                     |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                     |
| TALC   | 014807966 |              |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 114          |             | 08/31/95         | 600 | 0.95MG - 94.2MG     |
| ORAL; CAPSULE, COATED PELLETS                  |           | 1            |             |                  |     |                     |
| ORAL; CAPSULE, ENTERIC COATED PELLETS          |           | 2            |             | 05/10/95         | 180 |                     |
| ORAL; CAPSULE, HARD GELATIN                    |           | 4            |             | 12/06/95         | 530 | 6.4MG - 40.0MG      |
| ORAL; CAPSULE, SUSTAINED ACTION                |           | 43           |             | 09/11/95         | 110 | 0.1MG - 122.06MG    |
| ORAL; DROPS                                    |           | 1            |             |                  |     |                     |
| ORAL; GRANULE, ENTERIC COATED                  |           | 1            |             |                  |     |                     |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                     |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 253          |             | 09/29/95         | 600 | 0.002GM - 0.008GM   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 3            |             | 05/14/82         | 520 | 6.0MG - 18.0MG      |
| ORAL; TABLET, COATED                           |           | 44           |             | 05/19/92         | 110 | 0.01MG - 25.0MG     |
| ORAL; TABLET, CONTROLLED RELEASE               |           | 1            |             |                  |     |                     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 9            |             | 06/19/95         | 520 | 4.7MG - 33.3MG      |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 1            |             |                  |     |                     |



INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|--|-----------|--------------|-------------|------------------|-----|-------------------|
| TALC   | 014807966 | 27           |             | 11/30/95         | 600 | 0.189MG - 204.0MG |
| ORAL; TABLET, FILM COATED                                    |           | 2            |             | 03/31/81         | UNK | 73.933MG          |
| ORAL; TABLET, REPEAT ACTION                                  |           | 25           |             | 11/14/94         | UNK | 0.1MG - 91.0MG    |
| ORAL; TABLET, SUSTAINED ACTION                               |           | 5            |             | 12/14/92         | 510 | 0.2MG - 3.0MG     |
| ORAL-21; TABLET  |           | 8            |             | 12/14/92         | 510 | 0.19MG - 3.0MG    |
| ORAL-28; TABLET  |           | 2            |             | 04/16/81         | 600 | 5.0MG             |
| SUBLINGUAL; TABLET   |           | 1            |             |                  |     |                   |
| TOPICAL; LOTION  |           | 1            |             |                  |     |                   |
| TOPICAL; OINTMENT  |           | 1            |             |                  |     |                   |
| TOPICAL; POWDER  |           | 1            |             |                  |     |                   |
| TOPICAL; SHAMPOO   |           | 1            |             |                  |     |                   |
| TALL OIL   | 008002264 | 1            |             |                  |     |                   |
| TOPICAL; SPONGE  |           |              |             |                  |     |                   |
| TALLOW GLYCERIDES  |           | 2            |             | 08/16/74         | 600 | 2.78%             |
| TOPICAL; EMULSION, CREAM                                     |           |              |             |                  |     |                   |
| TARTARIC ACID  | 000087694 | 1            |             |                  |     |                   |
| INTRAVENOUS; SOLUTION, INJECTION                             |           | 2            |             | 06/12/79         | 600 |                   |
| ORAL; TABLET   |           | 1            |             |                  |     |                   |
| ORAL; TABLET, SUSTAINED ACTION                               |           | 2            |             | 01/01/80         | 600 |                   |
| SUBLINGUAL; TABLET   |           |              |             |                  |     |                   |
| TARTARIC ACID, DL-   | 000133379 | 1            |             |                  |     |                   |
| IM - IV; INJECTION   |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                       |           | 1            |             |                  |     |                   |
| IV(INFUSION); INJECTION                                      |           | 1            |             |                  |     |                   |
| ORAL; SOLUTION, ELIXIR                                       |           | 1            |             |                  |     |                   |
| ORAL; SYRUP  |           | 1            |             |                  |     |                   |
| ORAL; TABLET   |           | 2            |             | 08/25/83         | 600 | 3.7MG - 3.96MG    |
| ORAL; TABLET, SUSTAINED ACTION                               |           | 1            |             |                  |     |                   |
| RECTAL; SUPPOSITORY  |           | 2            |             | 10/04/83         | 600 | 0.021GM           |
| SUBLINGUAL; TABLET   |           | 1            |             |                  |     |                   |
| VAGINAL; SUPPOSITORY   |           | 1            |             |                  |     |                   |
| TENOX  |           | 2            |             | 08/16/74         | 600 | 0.025%            |
| TOPICAL; EMULSION, CREAM                                     |           | 2            |             | 10/01/84         | 600 | 0.025%            |
| TOPICAL; OINTMENT  |           |              |             |                  |     |                   |
| TERPENE RESIN  | 009003741 | 1            |             |                  |     |                   |
| ORAL; CAPSULE  |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                              |           |              |             |                  |     |                   |
| TERPINEOL, ALPHA   | 000098555 | 1            |             |                  |     |                   |
| TOPICAL; LOTION  |           |              |             |                  |     |                   |
| TETRAKIS(1-ISOCYANO-2-METHOXY-2-METHYL-PROPANE)-COPPER(I) TE |           | 1            |             |                  |     |                   |
| INTRAVENOUS; INJECTION                                       |           |              |             |                  |     |                   |
| THIAZOXIMIC ACID   |           | 1            |             |                  |     |                   |
| IM - IV; POWDER, FOR INJECTION SOLUTION                      |           | 1            |             |                  |     |                   |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION                 |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                       | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| THIMEROSAL  | 000054648 |              |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                              |           | 1            |             |                  |     |                   |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION           |           | 2            |             | 01/10/67         | 110 |                   |
| OPHTHALMIC; SOLUTION                                  |           | 13           |             | 12/29/95         | 600 | 0.001% - 0.01%    |
| OPHTHALMIC; SUSPENSION                                |           | 3            |             | 05/11/88         | 600 | 0.001%            |
| OTIC; SUSPENSION                                      |           | 4            |             | 09/29/87         | 600 | 0.002% - 0.01%    |
| SUBCUTANEOUS; INJECTION                               |           | 1            |             |                  |     |                   |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION          |           | 1            |             |                  |     |                   |
| TOPICAL; EMULSION, CREAM                              |           | 2            |             | 02/01/79         | 600 | 0.01%             |
| TOPICAL; LOTION                                       |           | 1            |             |                  |     |                   |
| TOPICAL; OINTMENT                                     |           | 1            |             |                  |     |                   |
| THIOGLYCEROL  | 000096275 |              |             |                  |     |                   |
| CAUDAL BLOCK; INJECTION                               |           | 1            |             |                  |     |                   |
| EPIDURAL; INJECTION                                   |           | 1            |             |                  |     |                   |
| INTRAMUSCULAR; INJECTION                              |           | 2            |             | 04/03/73         | 600 | 0.5%              |
| INTRAVENOUS; INJECTION                                |           | 10           |             | 11/22/91         | 600 | 0.2%              |
| NERVE BLOCK; INJECTION                                |           | 1            |             |                  |     |                   |
| THYMOL  | 000089838 |              |             |                  |     |                   |
| INHALATION; LIQUID                                    |           | 3            |             | 07/14/76         | 600 | 0.01%             |
| ORAL; POWDER, FOR RECONSTITUTION                      |           | 1            |             |                  |     |                   |
| TIMING SOLUTION CLEAR N-7                             |           |              |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                       |           | 4            |             | 04/11/89         | 600 | 26.2MG            |
| TITANIUM DIOXIDE                                      | 001309633 |              |             |                  |     |                   |
| INTRAUTERINE; SUPPOSITORY, INSERT, CONTROLLED RELEASE |           | 1            |             |                  |     |                   |
| OPHTHALMIC; DRUG DELIVERY SYSTEM                      |           | 1            |             |                  |     |                   |
| OPHTHALMIC; SUPPOSITORY, INSERT, CONTROLLED RELEASE   |           | 1            |             |                  |     |                   |
| ORAL; CAPLET  |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE   |           | 417          |             | 12/20/95         | 520 | 0.08MG - 338.0MG  |
| ORAL; CAPSULE, COATED PELLETS                         |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                 |           | 4            |             | 10/05/95         | 180 |                   |
| ORAL; CAPSULE, HARD GELATIN                           |           | 9            |             | 05/03/95         | 530 |                   |
| ORAL; CAPSULE, SOFT GELATIN                           |           | 9            |             | 11/22/95         | 150 | 0.17MG - 5.73MG   |
| ORAL; CAPSULE, SUSTAINED ACTION                       |           | 27           |             | 09/11/95         | 110 | 0.112MG - 0.884MG |
| ORAL; DROPS   |           | 1            |             |                  |     |                   |
| ORAL; GRANULE, FOR RECONSTITUTION                     |           | 1            |             |                  |     |                   |
| ORAL; POWDER, FOR RECONSTITUTION                      |           | 4            |             | 12/20/95         | 520 | 0.788% - 1.8%     |
| ORAL; TABLET  |           | 356          |             | 10/06/95         | UNK | 0.00069GM         |
| ORAL; TABLET, COATED                                  |           | 49           |             | 12/30/92         | 110 | 0.04MG - 1.15MG   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED          |           | 8            |             | 04/10/95         | 520 | 0.08MG - 358.0MG  |
| ORAL; TABLET, ENTERIC COATED PARTICLES                |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                             |           | 99           |             | 12/27/95         | 150 | 0.34MG - 12.5MG   |
| ORAL; TABLET, SUSTAINED ACTION                        |           | 40           |             | 03/30/95         | 110 | 0.7MG - 6.221MG   |
| ORAL-21; TABLET                                       |           | 2            |             | 12/14/92         | 510 | 0.12MG            |
| ORAL-28; TABLET                                       |           | 5            |             | 11/17/95         | 510 | 0.1MG - 0.995MG   |
| TOPICAL; EMULSION, CREAM                              |           | 17           |             | 04/01/94         | UNK | 0.5% - 3.0%       |
| TOPICAL; LOTION                                       |           | 1            |             |                  |     |                   |
| TOPICAL; OINTMENT                                     |           | 4            |             | 10/10/85         | 600 | 3.0% - 5.0%       |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                           | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE     |
|---|-----------|--------------|-------------|------------------|-----|-------------------|
| TITANIUM DIOXIDE<br>TOPICAL; SUSPENSION, SHAMPOO          | 001309633 | 3            |             | 01/10/91         | 600 | 5.0%              |
| TOCOPHEROL<br>ORAL; CAPSULE                               | 001406662 | 1            |             |                  |     |                   |
| TOPICAL; OINTMENT   |           | 1            |             |                  |     |                   |
| TRAGACANTH<br>ORAL; POWDER, FOR RECONSTITUTION            | 009000651 | 1            |             |                  |     |                   |
| ORAL; SUSPENSION  |           | 5            |             | 08/11/80         | 600 |                   |
| ORAL; SYRUP   |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 3            |             | 12/14/60         | 510 | 4.0MG             |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED              |           | 1            |             |                  |     |                   |
| TRIACETIN<br>ENDOCERVICAL; GEL                            | 000102761 | 1            |             |                  |     |                   |
| ORAL; CAPLET  |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, COATED PELLETS                             |           | 1            |             |                  |     |                   |
| ORAL; CAPSULE, ENTERIC COATED PELLETS                     |           | 1            |             |                  |     |                   |
| ORAL; TABLET  |           | 28           |             | 01/27/94         | 600 | 0.22MG - 2.926MG  |
| ORAL; TABLET, COATED                                      |           | 5            |             | 10/03/77         | 600 | 0.213MG - 0.85MG  |
| ORAL; TABLET, CONTROLLED RELEASE                          |           | 1            |             |                  |     |                   |
| ORAL; TABLET, FILM COATED                                 |           | 8            |             | 12/19/95         | 180 | 1.5MG - 15.12MG   |
| ORAL; TABLET, SUSTAINED ACTION                            |           | 2            |             | 12/02/85         | 600 | 1.42MG - 1.96MG   |
| TRIBEHENIN<br>ORAL; TABLET                                | 018641571 | 1            |             |                  |     |                   |
| TRICHLOROMONOFUOROMETHANE<br>INHALATION; AEROSOL, METERED | 000075694 | 17           |             | 12/28/95         | 600 | 24.47% - 34.2805% |
| NASAL; AEROSOL, METERED                                   |           | 3            |             | 02/14/94         | UNK |                   |
| ORAL; AEROSOL SPRAY                                       |           | 1            |             |                  |     |                   |
| TRIDECETH 10<br>TOPICAL; EMULSION, AEROSOL FOAM           |           | 1            |             |                  |     |                   |
| TOPICAL; SOLUTION   |           | 1            |             |                  |     |                   |
| TRIETHYL CITRATE<br>ORAL; CAPSULE, ENTERIC COATED PELLETS | 000077930 | 1            |             |                  |     |                   |
| ORAL; CAPSULE, SUSTAINED ACTION                           |           | 3            |             | 01/04/95         | 600 | 1.2MG - 3.6MG     |
| ORAL; TABLET  |           | 1            |             |                  |     |                   |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,            |           | 1            |             |                  |     |                   |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED              |           | 2            |             | 06/19/95         | 520 | 1.65MG            |
| ORAL; TABLET, SUSTAINED ACTION                            |           | 2            |             | 05/24/83         | 600 | 1.6MG             |
| TRIGLYCERIDE, SYNTHETIC<br>ORAL; CAPSULE                  |           | 1            |             |                  |     |                   |
| TRIHYDROXYSTEARIN<br>TOPICAL; EMULSION, CREAM             |           | 1            |             |                  |     |                   |
| TRILANETH-4 PHOSPHATE<br>TOPICAL; OINTMENT                |           | 1            |             |                  |     |                   |
| TRILAURETH 4 PHOSPHATE<br>TOPICAL; OINTMENT               |           | 1            |             |                  |     |                   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM  | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|--|-----------|--------------|-------------|------------------|-----|-----------------|
| TRIMYRISTIN<br>ORAL; TABLET  |           | 1            |             |                  |     |                 |
| TRISTEARIN<br>ORAL; CAPSULE  | 000555431 | 1            |             |                  |     |                 |
| TRITHIAZOXIMIC ACID<br>IM - IV; POWDER, FOR INJECTION SOLUTION                   |           | 1            |             |                  |     |                 |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION                                     |           | 1            |             |                  |     |                 |
| TRITON X-200 SODIUM SALT OF ALKYL LAURYL POLYETHER SULFONATE<br>TOPICAL; SHAMPOO |           | 1            |             |                  |     |                 |
| TROLAMINE<br>RECTAL; EMULSION, AEROSOL FOAM                                      | 000102716 | 1            |             |                  |     |                 |
| TOPICAL; AEROSOL   |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, AEROSOL FOAM  |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM   |           | 3            |             | 06/13/88         | 600 | 0.25% - 1.0%    |
| TOPICAL; GEL   |           | 1            |             |                  |     |                 |
| TOPICAL; LOTION  |           | 8            |             | 12/01/92         | UNK | 0.25% - 1.8%    |
| TOPICAL; SPONGE  |           | 1            |             |                  |     |                 |
| VAGINAL; EMULSION, CREAM   |           | 2            |             | 01/21/87         | 520 | 0.75%           |
| TROLAMINE LAURYL SULFATE<br>TOPICAL; EMULSION, CREAM                             |           | 1            |             |                  |     |                 |
| TOPICAL; SHAMPOO   |           | 4            |             | 09/18/84         | 600 | 35.0% - 77.8%   |
| TROMETHAMINE<br>INTRA-ARTERIAL; INJECTION  | 000077861 | 2            |             | 05/10/95         | 160 | 0.242%          |
| INTRAMUSCULAR; INJECTION   |           | 1            |             |                  |     |                 |
| INTRATHECAL; INJECTION   |           | 2            |             | 06/30/89         | 160 | 0.1% - 0.121%   |
| INTRATHECAL; SOLUTION  |           | 1            |             |                  |     |                 |
| INTRAVASCULAR; INJECTION   |           | 4            |             | 05/10/95         | 160 | 0.121% - 0.36%  |
| INTRAVASCULAR; SOLUTION  |           | 1            |             |                  |     |                 |
| INTRAVENOUS; INJECTION   |           | 4            |             | 05/10/95         | 160 | 0.005% - 0.242% |
| INTRAVENOUS; SOLUTION  |           | 1            |             |                  |     |                 |
| IV(INFUSION); SOLUTION   |           | 1            |             |                  |     |                 |
| OPHTHALMIC; SOLUTION   |           | 2            |             | 11/04/93         | UNK | 0.091% - 0.936% |
| ORAL; SOLUTION   |           | 2            |             | 10/24/95         | 160 | 0.121%          |
| ORAL; TABLET   |           | 1            |             |                  |     |                 |
| RECTAL; SOLUTION   |           | 2            |             | 10/24/95         | 160 | 0.121%          |
| TOPICAL; SOLUTION  |           | 1            |             |                  |     |                 |
| TYLOXAPOL<br>OPHTHALMIC; SOLUTION  | 025301024 | 5            |             | 05/25/94         | 600 | 0.05% - 0.1%    |
| OPHTHALMIC; SUSPENSION   |           | 4            |             | 07/21/89         | UNK | 0.05% - 0.1%    |
| UNION 76 ANSCO-RES 6038<br>TRANSDERMAL; FILM, CONTROLLED RELEASE                 |           | 1            |             |                  |     |                 |
| UNSPECIFIED INGREDIENT<br>ORAL; CAPSULE  |           | 48           |             | 03/03/94         | 110 |                 |
| ORAL; CAPSULE, ENTERIC COATED PELLETS  |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SOFT GELATIN  |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION  |           | 12           |             | 02/08/95         | UNK |                 |
| ORAL; CONCENTRATE  |           | 1            |             |                  |     |                 |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE       |
|--|-----------|--------------|-------------|------------------|-----|---------------------|
| UNSPECIFIED INGREDIENT                         |           |              |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 2            |             | 04/23/79         | 600 |                     |
| ORAL; SOLUTION                                 |           | 6            |             | 05/15/87         | 600 |                     |
| ORAL; SUSPENSION                               |           | 2            |             | 03/18/87         | 600 |                     |
| ORAL; SYRUP                                    |           | 5            |             | 11/22/85         | 600 |                     |
| ORAL; TABLET                                   |           | 83           |             | 07/12/95         | 110 |                     |
| ORAL; TABLET, COATED                           |           | 25           |             | 06/20/88         | 600 |                     |
| ORAL; TABLET, FILM COATED                      |           | 6            |             | 12/08/86         | 110 |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 8            |             | 09/22/94         | 110 |                     |
| UREA   | 000057136 |              |             |                  |     |                     |
| INTRAMUSCULAR; INJECTION                       |           | 1            |             |                  |     |                     |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                     |
| VAGINAL; EMULSION, CREAM                       |           | 6            |             | 06/09/86         | 600 | 0.64%               |
| VAGINAL; TABLET                                |           | 1            |             |                  |     |                     |
| VANILLIN                                       | 000121335 |              |             |                  |     |                     |
| ORAL; POWDER, FOR RECONSTITUTION               |           | 4            |             | 12/23/91         | 520 | 0.07875%            |
| ORAL; SOLUTION                                 |           | 1            |             |                  |     |                     |
| ORAL; SOLUTION, ELIXIR                         |           | 1            |             |                  |     |                     |
| ORAL; SUSPENSION                               |           | 3            |             | 09/25/92         | 600 |                     |
| ORAL; SYRUP                                    |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 6            |             | 10/31/91         | 520 | 0.32MG - 1.5MG      |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 1            |             |                  |     |                     |
| ORAL; TABLET, COATED                           |           | 3            |             | 10/03/11         | 600 | 0.05MG - 0.16MG     |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED   |           | 2            |             | 10/26/86         | 120 | 0.4MG - 1.16MG      |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 1            |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                      |           | 4            |             | 09/28/77         | 600 |                     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 7            |             | 06/30/94         | 600 | 0.1664MG - 1.34MG   |
| VEGETABLE OIL                                  | 008008897 |              |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 1            |             |                  |     |                     |
| ORAL; GRANULE, FOR RECONSTITUTION              |           | 1            |             |                  |     |                     |
| ORAL; SUSPENSION, SUSTAINED ACTION             |           | 1            |             |                  |     |                     |
| ORAL; TABLET                                   |           | 4            |             | 03/04/77         | 600 | 1.3MG - 2.55MG      |
| ORAL; TABLET, ENTERIC COATED PARTICLES         |           | 1            |             |                  |     |                     |
| TOPICAL; EMULSION, CREAM                       |           | 1            |             |                  |     |                     |
| VEGETABLE OILS, HYDROGENATED                   | 068334281 |              |             |                  |     |                     |
| ORAL; CAPSULE                                  |           | 10           |             | 12/04/87         | 600 | 6.0MG - 82.0MG      |
| ORAL; CAPSULE, SOFT GELATIN                    |           | 3            |             | 11/22/95         | 150 | 30.3MG - 60.64MG    |
| ORAL; TABLET                                   |           | 32           |             | 12/29/93         | 600 | 0.93MG - 40.0MG     |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, |           | 2            |             | 10/04/76         | 600 | 8.0MG               |
| ORAL; TABLET, COATED                           |           | 1            |             |                  |     |                     |
| ORAL; TABLET, FILM COATED                      |           | 2            |             | 12/28/81         | 520 | 4.25MG - 12.3MG     |
| ORAL; TABLET, SUSTAINED ACTION                 |           | 3            |             | 12/15/88         | 600 | 63.0MG - 228.5MG    |
| RECTAL; SUPPOSITORY                            |           | 11           |             | 02/27/95         | 600 | 1.2963GM - 1.3706GM |
| VAGINAL; SUPPOSITORY                           |           | 5            |             | 11/19/93         | 600 | 690.0MG - 719.0MG   |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE   |
|---|-----------|--------------|-------------|------------------|-----|-----------------|
| VEGETABLE SHORTENING                          |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SOFT GELATIN                   |           | 1            |             |                  |     |                 |
| VINYL ACETATE - CROTONIC ACID COPOLYMER       |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION               |           | 1            |             |                  |     |                 |
| VINYL CHLORIDE                                | 000075014 | 1            |             |                  |     |                 |
| ORAL; TABLET                                  |           | 1            |             |                  |     |                 |
| VISCARIN                                      | 008047254 | 1            |             |                  |     |                 |
| ORAL; SYRUP                                   |           | 1            |             |                  |     |                 |
| VITAMIN E                                     | 000059029 | 1            |             |                  |     |                 |
| ORAL; CAPSULE                                 |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SOFT GELATIN                   |           | 1            |             |                  |     |                 |
| ORAL; SOLUTION                                |           | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                     |           | 1            |             |                  |     |                 |
| ORAL; TABLET, SUSTAINED ACTION                |           | 1            |             |                  |     |                 |
| ORAL-21; TABLET                               |           | 1            |             |                  |     |                 |
| ORAL-28; TABLET                               |           | 2            |             | 12/14/92         | 510 | 0.08MG          |
| WATER FOR INJECTION, BACTERIOSTATIC           |           | 1            |             |                  |     |                 |
| IM - IV; POWDER, FOR INJECTION SOLUTION       |           | 1            |             |                  |     |                 |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION |           | 1            |             |                  |     |                 |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION  |           | 1            |             |                  |     |                 |
| WAX   |           | 1            |             |                  |     |                 |
| ORAL; TABLET, FILM COATED                     |           | 1            |             |                  |     |                 |
| WAX BLEND                                     |           | 1            |             |                  |     |                 |
| ORAL; CAPSULE, SUSTAINED ACTION               |           | 1            |             |                  |     |                 |
| ORAL; TABLET                                  |           | 1            |             |                  |     |                 |
| WAX, DEHYDAG                                  | 008023403 | 1            |             |                  |     |                 |
| ORAL; TABLET, COATED                          |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                      |           | 1            |             |                  |     |                 |
| WAX, EMULSIFYING                              | 008014388 | 1            |             |                  |     |                 |
| RECTAL; EMULSION, AEROSOL FOAM                |           | 1            |             |                  |     |                 |
| TOPICAL; AEROSOL                              |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                      |           | 19           |             | 09/20/95         | UNK | 1.0% - 32.0%    |
| TOPICAL; LOTION                               |           | 1            |             |                  |     |                 |
| TOPICAL; OINTMENT                             |           | 5            |             | 10/01/84         | 600 | 0.75%           |
| WAX, WHITE                                    | 008006404 | 1            |             |                  |     |                 |
| ORAL; CAPSULE                                 |           | 6            |             | 05/10/93         | 180 | 1.4MG - 7.183MG |
| ORAL; CAPSULE, SUSTAINED ACTION               |           | 30           |             | 10/06/95         | UNK | 0.01MG - 0.25MG |
| ORAL; TABLET                                  |           | 23           |             | 09/10/87         | 600 | 0.018MG - 3.0MG |
| ORAL; TABLET, COATED                          |           | 1            |             |                  |     |                 |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED  |           | 1            |             |                  |     |                 |
| ORAL; TABLET, ENTERIC COATED PARTICLES        |           | 3            |             | 09/03/76         | 600 | 0.03MG - 0.2MG  |
| ORAL; TABLET, FILM COATED                     |           | 2            |             | 03/31/81         | UNK | 0.037MG         |
| ORAL; TABLET, REPEAT ACTION                   |           | 14           |             | 01/04/95         | 600 | 0.06MG - 14.0MG |
| ORAL; TABLET, SUSTAINED ACTION                |           | 2            |             | 09/02/77         | UNK | 187.5MG         |
| RECTAL; SUPPOSITORY                           |           | 1            |             |                  |     |                 |
| TOPICAL; CREAM, AUGMENTED                     |           | 1            |             |                  |     |                 |
| TOPICAL; EMULSION, CREAM                      |           | 10           |             | 08/03/94         | 600 | 1.25% - 5.0%    |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM                               | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE     | DIV          | POTENCY RANGE                        |
|---|-----------|--------------|-------------|----------------------|--------------|--------------------------------------|
| WAX, WHITE  | 008006404 | 5            |             | 04/30/87             | UNK          | 5.0% - 6.0%                          |
| TOPICAL; OINTMENT   |           | 2            |             | 08/31/95             | 600          | 6.0%                                 |
| TOPICAL; OINTMENT, AUGMENTED<br>VAGINAL; EMULSION, CREAM      |           | 1            |             |                      |              |                                      |
| WAX, YELLOW   | 008012893 | 1            |             |                      |              |                                      |
| ORAL; CAPSULE   |           | 1            |             |                      |              |                                      |
| ORAL; CAPSULE, SOFT GELATIN                                   |           | 4            |             |                      |              |                                      |
| ORAL; TABLET<br>ORAL; TABLET, COATED                          |           | 4            |             | 12/08/87<br>05/06/74 | 600<br>600   | 0.06MG - 0.075MG<br>0.15MG - 0.296MG |
| WECOBEE FS<br>VAGINAL; SUPPOSITORY                            |           | 1            |             |                      |              |                                      |
| WITEPSOL E-85<br>VAGINAL; TAMPON                              |           | 1            |             |                      |              |                                      |
| WITEPSOL W-35<br>RECTAL; SUPPOSITORY                          |           | 1            |             |                      |              |                                      |
| XANTHAN GUM   | 011138662 | 1            |             |                      |              |                                      |
| ORAL; CAPSULE   |           | 1            |             |                      |              |                                      |
| ORAL; DROPS   |           | 1            |             |                      |              |                                      |
| ORAL; GRANULE   |           | 1            |             |                      |              |                                      |
| ORAL; GRANULE, FOR RECONSTITUTION                             |           | 1            |             |                      |              |                                      |
| ORAL; POWDER  |           | 1            |             |                      |              |                                      |
| ORAL; POWDER, FOR RECONSTITUTION                              |           | 24           |             | 12/20/95             | 520          | 0.0004% - 1.6%                       |
| ORAL; SUSPENSION  |           | 11           |             | 06/16/95             | UNK          | 0.04%                                |
| ORAL; SUSPENSION, SUSTAINED ACTION                            |           | 1            |             |                      |              |                                      |
| ORAL; TABLET  |           | 1            |             |                      |              |                                      |
| RECTAL; ENEMA   |           | 1            |             |                      |              |                                      |
| TOPICAL; EMULSION, CREAM                                      | 6         |              | 09/04/92    | UNK                  | 0.3% - 0.75% |                                      |
| ZARZAROL  |           | 1            |             |                      |              |                                      |
| ORAL; PASTILLE  |           | 1            |             |                      |              |                                      |
| ORAL; SOLUTION  |           | 1            |             |                      |              |                                      |
| ORAL; SOLUTION, ELIXIR  |           | 1            |             |                      |              |                                      |
| ORAL; SUSPENSION  |           | 5            |             | 03/22/85             | 600          |                                      |
| ORAL; SYRUP   |           | 1            |             |                      |              |                                      |
| ORAL; TABLET  |           | 1            |             |                      |              |                                      |
| ZEIN  | 009010666 | 2            |             | 03/31/81             | UNK          | 4.71MG                               |
| ORAL; TABLET, REPEAT ACTION<br>ORAL; TABLET, SUSTAINED ACTION |           | 8            |             | 11/14/94             | UNK          | 4.5MG - 135.0MG                      |
| ZEDLEX<br>ORAL; TABLET, SUSTAINED ACTION                      |           | 1            |             |                      |              |                                      |
| ZINC ACETATE  | 000557346 | 3            |             | 06/25/91             | 510          | 0.015%                               |
| SUBCUTANEOUS; INJECTION                                       |           | 1            |             |                      |              |                                      |
| TOPICAL; LOTION   |           | 1            |             |                      |              |                                      |
| TOPICAL; SOLUTION<br>TOPICAL; SWAB                            |           | 1            |             |                      |              |                                      |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM              | CAS #     | NDA<br>COUNT | LAST<br>NDA | APPROVAL<br>DATE | DIV | POTENCY RANGE  |
|--|-----------|--------------|-------------|------------------|-----|----------------|
| ZINC CHLORIDE                                | 007646857 | 1            |             |                  |     |                |
| IM - SC; INJECTION                           |           | 3            |             |                  |     |                |
| INTRADERMAL; INJECTION                       |           | 5            |             | 02/08/77         | 510 | 7.4% - 23.0%   |
| SUBCUTANEOUS; INJECTION                      |           |              |             | 06/25/91         | 510 | 0.015% - 23.0% |
| ZINC OXIDE                                   | 001314132 | 1            |             |                  |     |                |
| IM - SC; INJECTION                           |           | 5            |             |                  |     |                |
| SUBCUTANEOUS; INJECTION                      |           | 1            |             | 06/25/91         | 510 | 0.0021% - 0.6% |
| SUBCUTANEOUS; SUSPENSION, INJECTION          |           |              |             |                  |     |                |
| ZINC STEARATE                                | 000557051 | 2            |             |                  |     |                |
| ORAL; CAPSULE                                |           | 11           |             | 03/04/86         | 600 | 1.0MG - 2.04MG |
| ORAL; TABLET                                 |           | 3            |             | 08/27/91         | 600 | 1.0MG - 7.1MG  |
| ORAL; TABLET, SUSTAINED ACTION               |           |              |             | 08/19/91         | UNK | 4.5MG - 29.0MG |
| ZINC SULFATE                                 | 007446200 | 1            |             |                  |     |                |
| ORAL; TABLET                                 |           |              |             |                  |     |                |
| 1-AMINOCYCLOHEXANECARBOXYLIC ACID, C-11      |           | 1            |             |                  |     |                |
| ORAL; CAPSULE                                |           |              |             |                  |     |                |
| 1,1,1-TRICHLOROETHANE                        | 000071556 | 1            |             |                  |     |                |
| ORAL; TABLET                                 |           |              |             |                  |     |                |
| 1,2,6-HEXANETRIOL                            | 000106694 | 5            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                     |           |              |             | 10/17/94         | 600 | 0.5% - 5.0%    |
| 1,3-DIMETHYLOL-5,5-DIMETHYL-HYDANTOIN        | 006440580 | 2            |             |                  |     |                |
| TOPICAL; LOTION                              |           |              |             | 11/26/85         | 600 | 0.4%           |
| 2-AMINO-2-METHYL-1-PROPANOL                  | 000124685 | 2            |             |                  |     |                |
| TOPICAL; EMULSION, CREAM                     |           | 4            |             | 12/19/74         | UNK | 1.0%           |
| TOPICAL; LOTION                              |           |              |             | 08/16/84         | 600 | 0.1% - 0.2%    |
| 2-ETHYL-HEXANOIC ACID                        |           | 1            |             |                  |     |                |
| IM - IV; POWDER, FOR INJECTION SOLUTION      |           |              |             |                  |     |                |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION |           |              |             |                  |     |                |
| 2-NAPTHOLENE SULFONATE SODIUM SALT           |           | 1            |             |                  |     |                |
| ORAL; SUSPENSION                             |           |              |             |                  |     |                |



## Appendix

These status lists provide current information concerning color additives, and will enable reviewers and others to determine the status and limitations of most color additives likely to be encountered in food, drug, device or cosmetic establishment.

To maintain concise form, this list is limited in many respects involving certification, regulations, labeling, etc. For specific details concerning these matters, please refer to the source documents, Code of Federal Regulations (CFR, Title 21, Parts 70 to 82) and to the Federal Food, Drug and Cosmetic Act, as amended, Sections 601(e), 602(e), 706, and as it pertains to Sections 201(s)(3) and (t), 402(c), 403(m), 501(a), and 502(m).

### PERMANENTLY LISTED COLOR ADDITIVES

|   |   |   |  |
|---|---|---|--|
| ALGAE MEAL, DRIED   | CHROMIUM-COBALT-ALUMINUM<br>OXIDE   | DYE DC RED #30                              | GRAPE SKIN EXTRACT (ENOCIANINA)            |
| ALUMINA   | CI VAT ORANGE 1   | DYE DC RED #31                              | GUANINE (PEARL ESSENCE)                    |
| ALUMINUM POWDER   | CITRUS RED #2   | DYE DC RED #33                              | GUATAZULENE (AZULENE)                      |
| ANNATTO   | COCHINEAL EXTRACT   | DYE DC RED #34                              | HENNA                                      |
| ANNATTO EXTRACT   | COPPER METALLIC POWDER  | DYE DC RED #36                              | IRON OXIDES                                |
| BEET JUICE  | CORN ENDOSPERM OIL  | DYE DC RED #39                              | IRON OXIDE, SYNTHETIC                      |
| BEET, DEHYDRATED  | COTTONSEED FLOUR, TOASTED,<br>PARTIALLY DEFATTED & COOKED   | DYE DC RED #8                               | LEAD ACETATE                               |
| BEET POWDER   | DIHYDROXYACETONE  | DYE DC RED #7                               | MANGANESE VIOLET-METHYL<br>UMBELLIFERONE   |
| BENZAMIDE,N,N'-(9,10-DIHYDRO-9,10-<br>DIOXO-1,8-ANTHRACENEDIYL)BIS- | DINAPHTHO[2,3-A:2'3'-<br>1]NAPHTH[2'3':6,7]INDOLO[2,3-<br>C]CARBAZOLE-5,10,15,17,22,24 -<br>HEXONE,16,23-DI-HYDRO | DYE DC VIOLET #2                            | MICA                                       |
| BENZENETRIOL,2-[[2,5-DIETHOXY-<br>4[[4-METHYLPHENYL]THIOPHENYL]]    | DISODIUM EDTA-COPPER  | DYE DC YELLOW #10                           | NORBIXIN                                   |
| BETA-APO-8'-CAROTENEAL  | DYE CARAMEL   | DYE DC YELLOW #11                           | ORANGE B                                   |
| BETA CAROTENE, NATURAL &<br>SYNTHETIC                               | DYE DC BLUE #4  | DYE DC YELLOW #7                            | PAPRIKA & PAPRIKA OLEORESIN                |
| BISMUTH CITRATE   | DYE DC BLUE #6  | DYE DC YELLOW #8                            | PHTHALOCYANINATO-2-COPPER                  |
| BISMUTH OXYCHLORIDE   | DYE DC BLUE #9  | DYE DC VIOLET #2                            | PHTHALOCYANINE GREEN                       |
| BIXIN   | DYE DC BROWN #1   | DYE EXT DC YELLOW #7                        | POLY(HYDROXYETHYLMETHACRYLAT<br>E)         |
| BRONZE POWDER   | DYE DC GREEN #5   | DYE EXT DC LAKES                            | -DYE COPOLYMERS                            |
| CALCIUM CARBONATE   | DYE-DC GREEN #6   | DYE FDC BLUE #1                             | PYROGALLOL                                 |
| CANTHAXANTHIN   | DYE DC GREEN #8   | DYE FDC BLUE #2                             | PYROPHYLLITE                               |
| CARAMEL   | DYE DC ORANGE #10   | DYE FDC GREEN #3                            | PYROPHYLLITE ALUMINUM SILICATE             |
| CARBAZOLE VIOLET  | DYE DC ORANGE #11   | DYE FDC RED #3                              | REACTIVE BLUE #19                          |
| CARMINE   | DYE DC ORANGE #4  | DYE FDC RED #40                             | RIBOFLAVIN                                 |
| CARMINE-CAROTENE  | DYE DC ORANGE #5  | DYE FDC YELLOW #10                          | SAFFERON (CROCUS SATIVUS L.)               |
| CARROT OIL  | DYE DC RED #17  | DYE FDC YELLOW #5                           | SILVER                                     |
| CHLOROPHYLLIN-COPPER COMPLEX  | DYE DC RED #21  | DYE FDC YELLOW #6                           | TAGETES MEAL & EXTRACT (AZTEC<br>MARIGOLD) |
| CHLOROPHYLLIN-COPPER COMPLEX,<br>OIL SOLUBLE                        | DYE DC RED #22  | DYE FDC YELLOW #7                           | TALC                                       |
| CHROMIUM HYDROXIDE, GREEN   | DYE DC RED #27  | FERRIC AMMONIUM CITRATE                     | TITANIUM DIOXIDE                           |
| CHROMIUM OXIDE GREENS   | DYE DC RED #28  | FERRIC AMMONIUM FERROCYANIDE<br>(IRON BLUE) | TUMERIC & TUMERIC OLEORESIN                |
|   |   | FERRIC FERROCYANIDE (IRON BLUE)             | ULTRAMARINE GREEN                          |
|   |   | FERROUS GLUCONATE                           | ULTRAMARINE PINK                           |
|   |   | FRUIT JUICE                                 |  |
|   |   | GRAPE COLOR EXTRACT                         |  |

ULTRAMARINE RED  
ULTRAMARINE VIOLET  
VEGETABLE JUICE  
XANTHOPHYLL  
ZINC OXIDE  
4-{2,4-DIMETHYLPHENYL}AZOL-2,4-  
DIHYDRO-5-METHYL-2-PHENYL-  
3H-PYRAZOL-3-ONE  
5,9,14,18-ANTHRAZINE  
9,10-ANTHRACENEDIONE,1,4-BIS[2-  
METHYLPHENYL] AMINO]  
6-ETHOXY-2-(6-ETHOXY-3-OXO-  
BENZO [b] THEIN-2-(3H)-YLIDENE)  
BENZO [b] THIOPHEN-3-(2H)-ONE  
1,4-BIS[4-(2-METHACRYLOXYETHYL)  
PHENYLAMINO]ANTHRAQUINONE  
16,23-DIHYDRODINAPHTHO[2,3-a:2',3'-  
i]NAPTH[2'3':6,7]INDOLO [2,3-  
c]CARBAZOLE-5,10,15,17,22,24-  
HEXONE  
N,N'-(9,10-DIHYDRO-9,10-DIOXO-1,5-  
ANTHRACENEDIYL) BISBENZAMIDE  
7,16-DICHLORO-4,15-DIHYDRO-  
5,9,14,18-ANTHRAZINETETRONE  
16,17-DIMETHOXYDINAPHTHO[1,2,3-  
cd:3',2',1',4m]PERYLENE-5,10-  
DIONE  
2-[(2,5-DIETHOXY-4-(4-  
METHYLPHENYL)THIOL)PHENYL]  
AZO]-1,3,5-BENZENETRIOL  
1,4-BIS[(2-METHYLPHENYL)AMINO]-  
9,10-ANTHRACENEDIONE

Appendix

PROVISIONALLY LISTED COLOR ADDITIVES

DINAPHTHO[1,2,3-CD:3'2',1']M-  
PERYLENE-5,10-DIONE,16,17-  
DIMETHOXY

DYE DC BLUE #2 LAKE  
DYE DC GREEN #3 LAKE  
DYE DC RED #21 LAKE  
DYE DC RED #27 AL LAKE  
DYE DC RED #30 AL LAKE  
DYE DC RED #30 LAKE  
DYE DC RED #33 LAKE  
DYE DC RED #6 LAKE  
DYE DC RED #7 CA LAKE  
DYE DC RED #7 LAKE  
DYE DC RED #8  
DYE DC VIOLET #2 LAKE  
DYE DC YELLOW #10 AL LAKE  
DYE DC YELLOW #10 HT LAKE  
DYE DC YELLOW #10 LAKE  
DYE DC YELLOW #5 LAKE  
DYE DC YELLOW #6  
DYE DC YELLOW #6 LAKE  
DYE FDC BLUE #1 AL LAKE  
DYE FDC BLUE #1 HT AL LAKE  
DYE FDC BLUE #1 LAKE  
DYE FDC BLUE #2  
DYE FDC RED #33  
DYE FDC RED #40 LAKE  
DYE FDC YELLOW #10 LAKE  
DYE FDC YELLOW #5 AL LAKE  
DYE FDC YELLOW #6

## Appendix

### DELISTED COLOR ADDITIVES

ALKANET (ALKANNA)  
 ALLOXAN  
 ALUMINUM BENZOATE  
 ALUMINUM HYDROXIDE  
 ALUMINUM STEARATE  
 B-METHYL-UMBELLIFERONE  
 BARIUM SULFATE  
 BENTONITE  
 BONE BLACK  
 BUTTER YELLOW  
 CALCIUM CARBONATE  
 CALCIUM SILICATE  
 CALCIUM STEARATE  
 CALCIUM SULFATE  
 CARBON BLACK (CHANNEL)  
 CARMINIC ACID  
 CHARCOAL  
 CHARCOAL (NFXI)  
 CHLOROPHYLL  
 CHLOROPHYLL-COPPER COMPLEX  
 COBALTOUS ALUMINATE (COBALT  
 BLUE)  
 COCHINEAL  
 CORNSTARCH  
 CUOBEAR  
 CURCUMIN  
 DYE DC BLACK #1  
 DYE DC BLUE #1 LAKE  
 DYE DC BLUE #3  
 DYE DC BLUE #5  
 DYE DC BLUE #6  
 DYE DC BLUE #7  
 DYE DC BLUE #8  
 DYE DC GREEN #1 LAKE  
 DYE DC GREEN #4  
 DYE DC GREEN #7  
 DYE DC ORANGE #12  
 DYE DC ORANGE #13  
 DYE DC ORANGE #14  
 DYE DC ORANGE #15

DYE DC ORANGE #16  
 DYE DC ORANGE #17  
 DYE DC ORANGE #3  
 DYE DC ORANGE #6  
 DYE DC ORANGE #7  
 DYE DC ORANGE #8  
 DYE DC ORANGE #9  
 DYE DC RED #10  
 DYE DC RED #11  
 DYE DC RED #12  
 DYE DC RED #13  
 DYE DC RED #14  
 DYE DC RED #15  
 DYE DC RED #16  
 DYE DC RED #18  
 DYE DC RED #19  
 DYE DC RED #2  
 DYE DC RED #2 LAKE  
 DYE DC RED #20  
 DYE DC RED #23  
 DYE DC RED #24  
 DYE DC RED #25  
 DYE DC RED #26  
 DYE DC RED #29  
 DYE DC RED #3  
 DYE DC RED #35  
 DYE DC RED #37  
 DYE DC RED #38  
 DYE DC RED #4  
 DYE DC RED #5  
 DYE DC RED #6  
 DYE DC RED #7  
 DYE DC RED #8  
 DYE DC RED #9  
 DYE DC VIOLET #1  
 DYE DC YELLOW #1  
 DYE DC YELLOW #2  
 DYE DC YELLOW #3  
 DYE DC YELLOW #4  
 DYE DC YELLOW #5

DYE DC YELLOW #5  
 DYE DC YELLOW #6  
 DYE DC YELLOW #8  
 DYE DC YELLOW #9  
 DYE EXT DC BLACK #1  
 DYE EXT DC BLUE #1  
 DYE EXT DC BLUE #2  
 DYE EXT DC BLUE #3  
 DYE EXT DC BLUE #4  
 DYE EXT DC BLUE #5  
 DYE EXT DC GREEN #1  
 DYE EXT DC ORANGE #1  
 DYE EXT DC ORANGE #2  
 DYE EXT DC ORANGE #3  
 DYE EXT DC ORANGE #4  
 DYE EXT DC RED #1  
 DYE EXT DC RED #2  
 DYE EXT DC RED #3  
 DYE EXT DC RED #8  
 DYE EXT DC RED #10  
 DYE EXT DC RED #11  
 DYE EXT DC RED #13  
 DYE EXT DC RED #14  
 DYE EXT DC RED #15  
 DYE EXT DC YELLOW #1  
 DYE EXT DC YELLOW #5  
 DYE EXT DC YELLOW #6  
 DYE EXT DC YELLOW #9  
 DYE EXT DC YELLOW #10  
 DYE FDC BLUE #8  
 DYE FDC GREEN #1  
 DYE FDC GREEN #1 LAKE  
 DYE FDC GREEN #2  
 DYE FDC ORANGE #1  
 DYE FDC ORANGE #2  
 DYE FDC RED #1  
 DYE FDC RED #2  
 DYE FDC RED #2 AL LAKE  
 DYE FDC RED #3  
 DYE FDC RED #3 AL LAKE

DYE FDC RED #3 LAKE  
 DYE FDC RED #4  
 DYE FDC RED #9  
 DYE FDC RED #32  
 DYE FDC VIOLET #1  
 DYE FDC VIOLET #1 LAKE  
 DYE FDC YELLOW #1  
 DYE FDC YELLOW #2  
 DYE FDC YELLOW #3  
 DYE FDC YELLOW #4  
 DYE LOGWOOD BLACK  
 FERRIC CHLORIDE  
 FERRIC HYDROXIDE  
 FERROUS SULFATE  
 FULLER'S EARTH  
 FUSTIC  
 GLOSS WHITE  
 GOLD  
 GRAPHITE  
 KAOLIN  
 KEISELGUHR (DIATOMITE)  
 LAPIS LAZULI (LAZURITE)  
 LITHIUM STEARATE  
 LITHOPONE  
 LOGWOOD, CHIPS & EXTRACT  
 LOGWOOD (GLUEWOOD, CAMPECHE  
 WOOD)  
 MAGNESIUM ALUMINUM SILICATE  
 MAGNESIUM CARBONATE  
 MAGNESIUM OXIDE  
 MAGNESIUM STEARATE  
 MAGNESIUM TRISILICATE  
 METALLIC SALTS  
 POTASSIUM FERROCYANIDE  
 SAFFLOWER (AMERICAN SAFFRON)  
 SAFFRON OLEORESIN  
 SIENNA  
 SILICIC ACID  
 SILICON DIOXIDE  
 TIN OXIDE

ULTRAMARINE BLUE  
UMBER  
VEGETABLE SUBSTANCES  
VERMICULITE  
ZINC CARBONATE  
ZINC STERATE  
ZIRCONIUM OXIDE  
ZIRCONIUM SILICATE  
4-METHYL-7-  
DIETHYLAMINOCOUMARIN (MDAC)