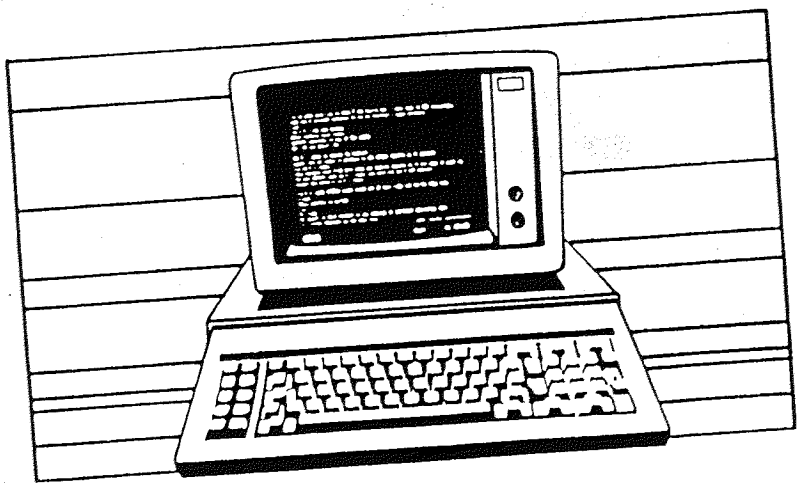
# INACTIVE INGREDIENT GUIDE



## 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 Brownewell |
| Division of Medical Imaging, Surgical, and Dental Products, HFD-160 | Herbert Thornton, R.Ph. |
| Division of Anesthesic, 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 Brownewell |
| 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

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS# |
|---|---|
| ACACIA<br>BUCCAL/SUBLINGUAL; TABLET<br>ORAL; CAPSULE<br>ORAL; CAPSULE, SUSTAINED ACTION<br>ORAL; POWDER | 009000015 |

| NDA COUNT | LAST NDA | APPROVAL DATE | DIVISION | POTENCY 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% |

**Ingredient** Chemical substance added to enhance formulation of given dosage forms. Component of product other than active ingredient.

**Route/Dosage Form** Formulation intended for the specified route of administration or site of application.

**CAS#** Registry number assigned to a compound by Chemical Abstracts Service on a random basis.

**NDA Count** Reflects total number of approved NDAs in which a parti- 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 COUNT | LAST NDA | APPROVAL 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 | | 05/07/78 | 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 | | 10/27/95 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| ACETIC ACID, GLACIAL | 000064197 | | | | | |
| ORAL; CONCENTRATE | | 2 | | 12/16/85 | 600 | 0.075% - 0.1% |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| OTIC; SOLUTION | | 1 | | | | |
| OTIC; SUSPENSION | | 2 | | 11/06/85 | 600 | 0.36% |
| SUBCUTANEOUS; INJECTION | | 2 | | 06/12/91 | 510 | 0.2% |
| ACETIC ANHYDRIDE | 000108247 | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| ACETONE SODIUM BISULFITE | 000540921 | | | | | |
| DENTAL; INJECTION | | 1 | | | | |
| INHALATION; SOLUTION | | 2 | | 06/30/81 | 600 | 0.4% - 0.50034% |
| NERVE BLOCK; INJECTION | | 3 | | 11/15/79 | 600 | 0.1% - 0.2% |
| ACETYL TRIBUTYL CITRATE | | | | | | |
| 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 | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; TABLET | | 33 | | 02/27/91 | 600 | 0.04MG - 2.7MG |
| ORAL; TABLET, COATED | | 2 | | 04/26/78 | 600 | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 2 | | 03/29/82 | 600 | 2.92MG - 5.17MG |
| ORAL; TABLET, FILM COATED | | 10 | | 02/02/87 | 600 | 0.04MG - 2.1MG |
| ORAL; TABLET, SUSTAINED ACTION | | 3 | | 05/14/85 | UNK | |
| ACETYLCYSTEINE | 000616911 | | | | | |
| INHALATION; SOLUTION | | 4 | | 11/22/88 | 600 | |
| ACRYLATES COPOLYMER | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| ADCOTE 72A103 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| AEROSIL 380 | | | | | | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| AEROSIL-200 | | | | | | |
| ORAL; TABLET | | 20 | | 08/17/88 | 600 | 0.1MG - 9.0MG |
| ORAL; TABLET, FILM COATED | | 2 | | 02/02/87 | 600 | 3.6MG - 7.2MG |
| AEROTEX RESIN 3730 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| AIR | | | | | | |
| INHALATION; GAS | | 3 | | 10/01/82 | 160 | |
| ALBUMIN AGGREGATED | | | | | | |
| INTRAVENOUS; INJECTION | | 5 | | 12/30/87 | 160 | 0.025% |
| ALBUMIN COLLOIDAL | | | | | | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| AMMONIUM ACETATE | 000631618 | | | | | |
| INTRAMUSCULAR; INJECTION | | 3 | | 01/27/95 | 600 | 0.4% |
| INTRAVENOUS; INJECTION | | 3 | | 01/27/95 | 600 | 0.4% |
| AMMONIUM CALCIUM ALGINATE | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| AMMONIUM CHLORIDE | 012125029 | | | | | |
| ORAL; TABLET | | 6 | | 06/09/87 | 600 | 2.4MG - 4.2MG |
| AMMONIUM HYDROXIDE | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| ORAL; CAPSULE | | 4 | | 05/16/95 | 600 | |
| SUBCUTANEOUS; INJECTION | | 1 | | | | |
| AMMONIUM PHOSPHATE, DIBASIC | 007783280 | | | | | |
| ORAL; TABLET | | 3 | | 11/02/87 | 600 | 0.4MG |
| AMMONIUM SALT OF C-12-C-15 LINEAR PRIMARY ALCOHOL ETHOXYLATE | | | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| AMMONIUM SULFATE | 007783202 | | | | | |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| INTRAVENOUS; SUSPENSION, INJECTION | | 1 | | | | |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| AMMONYX | | | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| AMPHOTERIC-2 | | | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 1 | | | | |
| AMPHOTERIC-6 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| ANETHOLE | 004180238 | | | | | |
| DENTAL; SOLUTION | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SOLUTION, ELIXIR | | 5 | | 10/03/83 | 600 | 0.003% |
| ANIDRISORB 85/70 | | | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 2 | | 04/20/95 | UNK | 30.045MG - 123.0MG |
| ANISE EXTRACT | 000104461 | | | | | |
| ORAL; SOLUTION, ELIXIR | | 2 | | 03/26/76 | 600 | |
| ANISE OIL | 008007703 | | | | | |
| ORAL; PASTILLE | | 1 | | | | |
| ORAL; SOLUTION, ELIXIR | | 2 | | 12/16/83 | 600 | |
| ORAL; SUSPENSION | | 1 | | | | |
| ANISE, STAR | | | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| ANOXID SBN | | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 10/31/94 | 600 | 0.15625% |
| ANTIFOAM | 008051089 | | | | | |
| ORAL; SUSPENSION | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| ANTIFOAM DC | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ANTIPYRINE | 000060800 | | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| AQUACOAT | | | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| AQUACOAT ECD | | | | | | |
| ORAL; TABLET, FILM COATED | | 2 | | 10/03/90 | 600 | |
| AQUAPHOR | 008029150 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| ARGININE | | | | | | |
| IM - IV; INJECTION | | 3 | | 03/31/92 | 600 | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 3 | | 11/07/95 | 600 | 0.78% - 1.56% |
| ARLATONE 289 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| ASCORBIC ACID | 000050817 | | | | | |
| 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 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |
| RECTAL; SUPPOSITORY | | 5 | | 08/14/87 | 600 | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| ASPARTAME | 053906697 | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| ASPARTAME | 053906697 | | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 3 | | 11/16/94 | UNK | 5.41MG - 40.0MG |
| ASPARTIC ACID | 000056848 | | | | | |
| IV(INFUSION); INJECTION | | 2 | | 02/18/94 | 180 | 0.4% - 0.68% |
| BALSAM CANADA | 008007474 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| BALSAM, FIR | | | | | | |
| TOPICAL; OIL | | 1 | | | | |
| BARIUM SULFATE | 007727437 | | | | | |
| INTRAUTERINE; SUPPOSITORY, INSERT, CONTROLLED RELEASE | | 1 | | | | |
| BEESWAX | | | | | | |
| 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 | 0.01/MG - 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 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| BENTONITE | 001302789 | | | | | |
| ORAL; CAPSULE | | 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 | 000100527 | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| BENZALKONIUM CHLORIDE | 008001545 | | | | | |
| INHALATION; SOLUTION | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| BENZENESULFONIC ACID | | | | | | |
| SOLUTION | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 12/20/95 | 520 | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 9 | | 08/02/88 | UNK | 1.231MG |
| ORAL; CONCENTRATE | | 1 | | | | |
| 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 | 0.96MG - 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| BETA-NAPHTHOL | 000135193 | | | | | |
| ORAL; CAPSULE | | 2 | | 01/13/76 | 600 | |
| BORIC ACID | 010043353 | | | | | |
| INTRAVENOUS; SOLUTION, INJECTION | | 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 | | | | | | |
| 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 | | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| SUBCUTANEOUS; SOLUTION, INJECTION | | 1 | | | | |
| BUTANE | 000106978 | | | | | |
| TOPICAL; AEROSOL SPRAY | | 1 | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| BUTYL ALCOHOL, TERTIARY | 000075650 | | | | | |
| TOPICAL; GEL | | 1 | | | | |
| BUTYLATED HYDROXYANISOLE | 008003245 | | | | | |
| INTRAMUSCULAR; INJECTION | | 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 | 000128370 | | | | | |
| INHALATION; LIQUID | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| BUTYLATED HYDROXYTOLUENE | 000128370 | | | | | |
| ORAL; CAPSULE | | 2 | | 08/17/78 | 510 | 0.016MG - 0.2MG |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| ORAL; TABLET | | 5 | | 12/11/87 | 600 | 0.1MG - 0.4MG |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| RECTAL; SUPPOSITORY | | 4 | | 08/31/92 | 600 | 0.0125MG - 0.213MG |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| 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 | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| BUTYLPARABEN | 000094268 | | | | | |
| 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 | | 09/23/74 | 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 | | 04/29/94 | 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 | | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| CALCIUM | 007440702 | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| CALCIUM ACETATE | 000062544 | | | | | |
| ORAL-21; TABLET | | 3 | | 04/12/88 | 600 | 8.0MG - 8.3MG |
| ORAL-28; TABLET | | 5 | | 02/09/89 | 600 | 8.3MG - 10.0MG |
| TOPICAL; EMULSION, CREAM | | 3 | | 09/28/92 | 600 | |
| CALCIUM ASCORBATE | 005743271 | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| CALCIUM CARBONATE, PRECIPITATED | 000471341 | | | | | |
| ORAL; CAPSULE | | 2 | | 12/31/93 | 510 | 125.68MG - 224.7MG |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| CALCIUM CARBONATE, PRECIPITATED | 000471341 | | | | | |
| ORAL; TABLET, COATED | | 18 | | 02/25/92 | 600 | 0.72MG - 64.8MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 3 | | 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 | | | | | |
| CAUDAL BLOCK; INJECTION | | 1 | | | | |
| EPIDURAL; INJECTION | | 3 | | 12/01/86 | 600 | 0.033% |
| IM - IV; INJECTION | | 5 | | 05/02/88 | 600 | 0.004% |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| INTRAOCULAR; SOLUTION | | 2 | | 04/28/95 | 600 | 0.048% |
| 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 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| CALCIUM HYDROXIDE | 001305620 | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| CALCIUM LACTATE | 000814802 | | | | | |
| VAGINAL; TABLET | | 1 | | | | |
| CALCIUM PHOSPHATE | 010103465 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 23 | | 11/18/93 | 110 | 21.5MG - 160.0MG |
| ORAL; TABLET, COATED | | 3 | | 01/15/70 | 510 | |
| ORAL; TABLET, FILM COATED | | 4 | | 03/15/78 | 120 | 51.5MG - 362.0MG |
| ORAL; TABLET, REPEAT ACTION | | 1 | | | | |
| ORAL-21; TABLET | | 2 | | 12/30/81 | 510 | 82.9MG - 86.0MG |
| ORAL-28; TABLET | | 2 | | 12/30/81 | 510 | 86.0MG |
| CALCIUM PHOSPHATE DIBASIC DIHYDRATE-SUCROSE AGGLOMERATE | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| CALCIUM PHOSPHATE, DIBASIC | 007757939 | | | | | |
| ORAL; CAPSULE | | 2 | | 04/10/84 | 600 | 1.8MG - 2.4MG |
| ORAL; CAPSULE, SUSTAINED ACTION | | 2 | | 04/18/62 | 120 | 5.0MG - 234.04MG |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 07/13/87 | UNK | 100.0MG |
| ORAL-28; TABLET | | 1 | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| CALCIUM SULFATE DIHYDRATE | 010101414 | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | -- | | |
| CALCIUM SULFATE, ANHYDROUS | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, COATED | | 2 | | 01/26/84 | 510 | |
| ORAL-28; TABLET | | 1 | | | | |
| CALDIAMIDE SODIUM | 122760912 | | | | | |
| INTRAVENOUS; SOLUTION, INJECTION | | 1 | | | | |
| CALTERIDOL CALCIUM | 121915831 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| CANDELILLA WAX | | | | | | |
| ORAL; TABLET | | 6 | | 11/19/91 | 110 | 0.05MG - 0.316MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 05/24/83 | 600 | |
| CANOLA OIL | 008002139 | | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| CAPRYLIC/CAPRIC DIGLYCERYL SUCCINATE | | | | | | |
| ORAL; AEROSOL | | 1 | | | | |
| CAPRYLIC/CAPRIC TRIGLYCERIDE | | | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| TOPICAL; AEROSOL SPRAY | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| CARAMEL | 008028895 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; GRANULE | | 1 | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SOLUTION | | 3 | | 12/03/86 | 600 | |
| ORAL; SYRUP | | 4 | | 03/02/87 | 600 | |
| RECTAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| CARBOMER | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 08/12/81 | 600 | 96.0MG |
| CARBOMER 1342 | 009003014 | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| CARBOMER 934 | 009007163 | | | | | |
| ORAL; SUSPENSION | | 2 | | 08/29/78 | 120 | |
| RECTAL; ENEMA | | 2 | | 05/27/94 | 600 | |
| TOPICAL; EMULSION, CREAM | | 4 | | 06/06/84 | 600 | 0.9% |
| TOPICAL; GEL | | 1 | | | | |
| TOPICAL; LOTION | | 12 | | 09/30/94 | 600 | 0.25% - 0.4% |
| TOPICAL; OINTMENT | | 1 | | | | |
| TOPICAL; SOLUTION | | 2 | | 12/15/95 | 600 | 0.15% |
| CARBOMER 934P | | | | | | |
| OPHTHALMIC; SUSPENSION | | 2 | | 12/30/94 | UNK | 0.2% |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| CARBOXYMETHYLCELLULOSE CALCIUM | 009050048 | | | | | |
| ORAL; TABLET | | 2 | | 02/21/92 | 520 | 4.0MG - 80.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| CARBOXYMETHYLCELLULOSE SODIUM | 009004324 | | | | | |
| 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 | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| RECTAL; ENEMA | | 1 | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| CARDAMOM | | | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| CARMINE | 008022933 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, UNCOATED, TROCHE | | 1 | | | | |
| CARMINE SOLUTION | 008001807 | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| CARMINIC ACID | 000476391 | | | | | |
| ORAL; TABLET | | 1 | | | | |

# INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 07/28/88 | 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 | 530 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| CELLULOSE, MICROCRYSTALLINE | 009004346 | | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 13 | | 04/28/95 | 600 | 0.5% - 2.0% |
| ORAL; SUSPENSION | | 9 | | 09/15/95 | 180 | 1.2% |
| ORAL; TABLET | | 1,407 | | 12/29/95 | 600 | 0.064GM - 0.152GM |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 6 | | 09/11/95 | 600 | 42.07MG - 505.0MG |
| ORAL; TABLET, COATED | | 37 | | 06/23/95 | 600 | 1.0MG - 107.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 8 | | 11/30/95 | 600 | 25.0MG - 125.71MG |
| ORAL; TABLET, DISPERSIBLE | | 2 | | 04/28/95 | 600 | |
| ORAL; TABLET, ENTERIC COATED PARTICLES | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 90 | | 12/19/95 | 180 | 5.0MG - 160.22MG |
| ORAL; TABLET, SUSTAINED ACTION | | 14 | | 11/18/94 | UNK | 23.45MG - 226.0MG |
| ORAL; TABLET, UNCOATED, TROCHE | | 1 | | | | |
| ORAL-21; TABLET | | 8 | | 12/13/93 | 600 | 19.6MG - 20.0MG |
| ORAL-28; TABLET | | 19 | | 11/17/95 | 510 | 7.58MG - 20.0MG |
| RECTAL; SUSPENSION | | 1 | | | | |
| SUBLINGUAL; TABLET | | 9 | | 02/26/88 | 600 | 6.0MG - 32.0MG |
| VAGINAL; TABLET | | 2 | | 10/17/85 | 600 | 320.0MG - 390.0MG |
| CELLULOSE, OXIDIZED | | | | | | |
| ORAL; TABLET | | 5 | | 10/03/74 | 600 | 0.03GM |
| CELLULOSIC POLYMERS | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, ENTERIC COATED PARTICLES | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| CERESIN | 008001750 | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| CETEARYL ALCOHOL | | | | | | |
| VAGINAL; SUPPOSITORY | | 1 | | | | |
| CETEARYL OCTANOATE | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| CETETH-10 | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| CETETH-2 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| CETETH-20 | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 06/24/75 | 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 | UNK | 0.5% |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 4 | | 08/31/81 | 600 | 0.2% - 0.5% |
| OTIC; SOLUTION | | 1 | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| CITRIC ACID | 000077929 | | | | | |
| CAUDAL BLOCK; INJECTION | | 1 | | | | |
| EPIDURAL; INJECTION | | 5 | | 02/26/93 | 600 | 0.02% |
| IM - IV - SC; INJECTION | | 10 | | 08/23/95 | 600 | 0.063% - 1.26% |
| IM - IV; INJECTION | | 21 | | 08/31/90 | 600 | 0.01% - 0.8% |
| IM - IV; SOLUTION, INJECTION | | 1 | | | | |
| IM - SC; INJECTION | | 1 | | | | |
| INHALATION; SOLUTION | | 4 | | 02/19/92 | UNK | 0.44042% - 1.0% |
| INTRA-ARTERIAL; SOLUTION, INJECTION | | 1 | | | | |
| INTRA-ARTICULAR; INJECTION | | 8 | | 04/09/86 | 600 | 0.205% |
| INTRABURSAL; INJECTION | | 4 | | 02/13/74 | 600 | 1.0% |
| INTRACARDIAC; INJECTION | | 1 | | | | |
| INTRALESIONAL; INJECTION | | 2 | | 02/17/84 | 600 | |
| INTRAMUSCULAR; INJECTION | | 17 | | 04/03/87 | 600 | 0.02% - 2.0% |
| INTRAPLEURAL; INJECTION | | 1 | | | | |
| INTRASYNOVIAL; INJECTION | | 2 | | 02/17/84 | 600 | 1.0% |
| INTRATHECAL; INJECTION | | 1 | | | | |
| INTRAVASCULAR; SOLUTION, INJECTION | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 28 | | 12/15/95 | 600 | 0.0175% - 0.86% |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 3 | | 07/12/88 | 600 | |
| INTRAVENOUS; SOLUTION, INJECTION | | 1 | | | | |
| IONTOPHORESIS; SOLUTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 32 | | 08/30/95 | 600 | 0.0229% - 1.0% |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 2 | | 08/31/95 | 600 | |
| NASAL; SOLUTION | | 1 | | | | |
| NASAL; SPRAY, METERED | | 3 | | 03/08/95 | UNK | 0.1% |
| NERVE BLOCK; INJECTION | | 15 | | 02/26/93 | 600 | 0.02% |
| OPHTHALMIC; SOLUTION | | 5 | | 01/04/95 | 600 | 0.035% - 0.05% |
| OPHTHALMIC; SUSPENSION | | 4 | | 05/09/89 | 600 | |
| ORAL; CAPSULE | | 6 | | 08/18/95 | 600 | 5.0MG - 12.8MG |
| ORAL; CAPSULE, HARD GELATIN | | 1 | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 2 | | 12/30/86 | 150 | 0.015MG - 1.0MG |
| ORAL; CONCENTRATE | | 10 | | 01/30/92 | 600 | 0.05% - 0.24% |
| ORAL; DROPS | | 3 | | 05/25/95 | UNK | 0.18% |
| ORAL; GRANULE | | 4 | | 06/15/88 | 600 | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; POWDER | | 2 | | 12/05/88 | 510 | 0.0005% |
| ORAL; POWDER, FOR RECONSTITUTION | | 28 | | 12/23/93 | 530 | |
| ORAL; SOLUTION | | 32 | | 11/17/95 | 530 | 0.0121% - 0.65% |
| ORAL; SOLUTION, ELIXIR | | 15 | | 10/27/92 | 600 | 0.0299% - 0.15% |
| ORAL; SUSPENSION | | 30 | | 06/16/95 | UNK | 0.1% - 0.2% |
| ORAL; SYRUP | | 79 | | 09/25/95 | 600 | 0.1% - 7.3519% |
| ORAL; TABLET | | 33 | | 03/20/92 | 600 | 0.06MG - 20.0MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 5 | | 11/16/94 | UNK | 0.2MG - 2.13MG |
| ORAL; TABLET, COATED | | 2 | | 04/08/81 | 600 | |
| ORAL; TABLET, FILM COATED | | 9 | | 12/23/91 | 510 | 1.25MG - 20.0MG |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 02/27/79 | 600 | 0.205% |
| SUBLINGUAL; TABLET | | 2 | | 08/11/81 | 600 | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 32 | | 06/13/95 | 600 | 0.001% - 0.85% |
| TOPICAL; GEL | | 1 | | | | |
| TOPICAL; LOTION | | 9 | | 01/24/92 | 600 | 0.21% - 0.65% |
| TOPICAL; OINTMENT | | 3 | | 09/30/83 | UNK | 0.001% |
| TOPICAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| TOPICAL; SHAMPOO | | 2 | | 08/27/90 | 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 COUNT | LAST NDA | APPROVAL 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 | | | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| COCAMINE OXIDE | 061788907 | | | | | |
| 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 | | | | |
| COCOGLYCERIDES | | | | | | |
| 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 | | | | |
| CORIANDER 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 05/01/77 | 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 | | | | |
| CROSCARMELLOSE 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| CROSCARMELLOSE SODIUM | | | | | | |
| SUBLINGUAL; TABLET | | 5 | | 09/18/86 | 600 | 1.8MG - 6.5MG |
| CROSPOVIDONE | 009003398 | | | | | |
| IMPLANTATION; PELLET | | 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 | | 12/22/95 | 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 | 007758998 | | | | | |
| OTIC; SOLUTION | | 1 | | | | |
| OTIC; SUSPENSION | | 1 | | | | |
| CUPRIC SULFATE, ANHYDROUS | 007758987 | | | | | |
| OTIC; SOLUTION | | 1 | | | | |
| CYCLOMETHICONE | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| TOPICAL; CREAM, AUGMENTED | | 1 | | | | |
| CYSTEINE | | | | | | |
| IM - SC; INJECTION, SUSTAINED ACTION | | 1 | | | | |
| CYSTEINE HYDROCHLORIDE | 007048046 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| DC ANTIFOAM AF TRITURATION 1% ON SUCROSE | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| DEHYDROACETIC ACID | 000520456 | | | | | |
| TOPICAL; LOTION | | 2 | | 11/26/85 | 600 | 0.1% |
| DEHYMULS E | | | | | | |
| TOPICAL; OINTMENT | | 2 | | 12/17/90 | UNK | 5.0% - 7.5% |
| DENATONIUM BENZOATE | 003734336 | | | | | |
| TOPICAL; GEL | | 1 | | | | |
| DEOXYCHOLIC ACID | 000083443 | | | | | |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| DEXTRATES | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 05/24/79 | 600 | 4.4% - 5.0% |
| INTRAPERITONEAL; INJECTION | | 1 | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DIACETYLATED MONOGLYCERIDES | 008029923 | | | | | |
| ORAL; TABLET | | 48 | | 11/05/92 | 600 | 0.00003ML - 0.00006ML |
| ORAL; TABLET, COATED | | 2 | | 04/08/81 | 600 | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 6 | | 05/31/91 | 600 | 0.04MG - 1.1MG |
| DIATOMACEOUS EARTH | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| DIATRIZOIC ACID | 000117964 | | | | | |
| INTRA-ARTERIAL; INJECTION | | 2 | | 08/29/74 | 160 | |
| INTRA-ARTICULAR; INJECTION | | 1 | | | | |
| INTRACARDIAC; INJECTION | | 1 | | | | |
| INTRADISCAL; INJECTION | | 1 | | | | |
| INTRAUTERINE; SOLUTION | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 2 | | 08/29/74 | 160 | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| PERIARTICULAR; INJECTION | | 1 | | | | |
| URETERAL; SOLUTION | | 1 | | | | |
| DIAZOLYDINYLUREA | | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 12/27/90 | UNK | 0.2% |
| TOPICAL; LOTION | | 1 | | | | |
| DIBUTYL PHTHALATE | 000084742 | | | | | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| DIBUTYL SEBACATE | 000109433 | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 2 | | 08/19/88 | 600 | |
| ORAL; GRANULE, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 2 | | 10/03/90 | 600 | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| DICHLORODIFLUOROMETHANE | 000075718 | | | | | |
| INHALATION; AEROSOL, METERED | | 24 | | 12/28/95 | 600 | 11.25% - 68.5611% |
| NASAL; AEROSOL SPRAY | | 1 | | | | |
| NASAL; AEROSOL, METERED | | 4 | | 02/14/94 | UNK | 99.789% |
| ORAL; AEROSOL | | 1 | | | | |
| RECTAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; AEROSOL | | 1 | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| DICHLOROFLUOROMETHANE | 000075434 | | | | | |
| ORAL; AEROSOL SPRAY | | 1 | | | | |
| DICHLOROTETRAFLUOROETHANE | 000076142 | | | | | |
| INHALATION; AEROSOL, METERED | | 15 | | 12/30/92 | UNK | 21.857% - 51.12% |
| NASAL; AEROSOL SPRAY | | 1 | | | | |
| NASAL; AEROSOL, METERED | | 1 | | | | |
| ORAL; AEROSOL | | 1 | | | | |
| RECTAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; AEROSOL | | 2 | | 05/17/88 | 600 | 50.0% |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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% |
| DIISOPROPYLBENZOTHIAZYL-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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DIOCTYLPHTHALATE | | | | | | |
| OPHTHALMIC; DRUG DELIVERY SYSTEM | | 1 | | | | |
| OPHTHALMIC; SUPPOSITORY, INSERT, CONTROLLED RELEASE | | 1 | | | | |
| DIPROPYLENE GLYCOL | 000110985 | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| DISODIUM EDISYLATE | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |
| DISODIUM MONOOLEAMIDE SULFASUCCINATE | | | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| DISOFENIN | 065717977 | | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| DOCUSATE | 010041197 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| DOCUSATE SODIUM | 000577117 | | | | | |
| INTRAMUSCULAR; INJECTION | | 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 | | | | | | |
| 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 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| DRY FLO | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| DURO-TAK 280-2516 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| DURO-TAK 80-1196 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| DUSTING POWDER | | | | | | |
| ORAL; TABLET | | 3 | | 04/14/83 | 600 | |
| ORAL; TABLET, COATED | | 1 | | | | |
| DYE BEIGE P-1437 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| DYE BLACK | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE DC RED #33 | 003567666 | | | | | |
| ORAL; CAPSULE | | 28 | | 03/03/94 | 110 | 0.0001MG |
| ORAL; CAPSULE, HARD GELATIN | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 4 | | 07/03/85 | 110 | 0.0013MG |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; SOLUTION | | 2 | | 04/27/88 | 510 | |
| ORAL; SOLUTION, ELIXIR | | 7 | | 12/16/83 | 600 | |
| ORAL; SUSPENSION | | 2 | | 12/18/80 | 600 | |
| ORAL; SYRUP | | 13 | | 03/07/85 | 600 | 0.001848% |
| ORAL; TABLET | | 8 | | 06/16/88 | 110 | 0.007MG - 0.15MG |
| TOPICAL; SHAMPOO | | 1 | | | | |
| DYE DC RED #33 LAKE | | | | | | |
| ORAL; CAPSULE | | 3 | | 02/25/88 | 600 | 1.79MG |
| ORAL; SYRUP | | 3 | | 11/22/85 | 600 | |
| DYE DC RED #36 | | | | | | |
| ORAL; TABLET | | 3 | | 09/07/77 | 110 | 0.01MG - 48.75MG |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| DYE DC RED #39 | 006371557 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| DYE DC RED #4 LAKE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| DYE DC RED #40 LAKE | | | | | | |
| ORAL; CAPSULE | | 4 | | 03/02/92 | 600 | |
| 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 | | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| DYE DC RED #6 LAKE | | | | | | |
| ORAL; TABLET | | 2 | | 03/01/90 | 180 | 0.4MG |
| DYE DC RED #7 | 005281049 | | | | | |
| ORAL; TABLET | | 10 | | 12/21/93 | 600 | 0.16MG - 0.6MG |
| ORAL; TABLET, COATED | | 2 | | 01/26/84 | 510 | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| DYE DC RED #7 CALCIUM LAKE | | | | | | |
| ORAL; CAPSULE | | 2 | | 12/20/90 | 110 | |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 1 | | | | |
| ORAL; CAPSULE, HARD GELATIN | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; TABLET | | 14 | | 12/21/93 | 600 | |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE DC RED #7 CALCIUM LAKE | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 01/16/85 | 600 | |
| DYE DC RED #7 LAKE | | | | | | |
| ORAL; TABLET | | 4 | | 01/25/88 | 600 | 0.02MG - 0.6MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| DYE DC RED LAKE | | | | | | |
| ORAL; TABLET | | 6 | | 09/25/95 | 600 | 0.009MG - 2.4MG |
| DYE DC VIOLET #2 LAKE | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| DYE DC YELLOW | | | | | | |
| ORAL; CAPSULE | | 3 | | 07/31/92 | 600 | |
| DYE DC YELLOW #10 | 008004920 | | | | | |
| BUCCAL; GUM, CHEWING | | 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 | | 05/27/95 | 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 | | 08/17/90 | 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 | | | | | | |
| ORAL; CAPLET | | 1 | | | | |
| ORAL; CAPSULE | | 7 | | 08/15/94 | 180 | |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 1 | | | | |
| ORAL; TABLET | | 72 | | 10/17/95 | 600 | 0.008MG - 2.5MG |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE DC YELLOW #10 ALUMINUM LAKE | | | | | | |
| ORAL; TABLET, COATED | | 8 | | 03/07/77 | 600 | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 7 | | 04/14/95 | 110 | 0.0075MG - 0.045MG |
| ORAL; TABLET, REPEAT ACTION | | 2 | | 03/31/81 | UNK | |
| ORAL; TABLET, SUSTAINED ACTION | | 6 | | 07/31/92 | 600 | |
| ORAL-21; TABLET | | 2 | | 01/29/87 | 600 | 0.096MG - 0.415MG |
| ORAL-28; TABLET | | 12 | | 07/03/92 | 510 | 0.096MG - 0.415MG |
| DYE DC YELLOW #10 HT LAKE | | | | | | |
| ORAL; TABLET | | 5 | | 06/13/88 | 600 | 0.1MG - 1.4MG |
| DYE DC YELLOW #10 LAKE | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; TABLET | | 74 | | 08/29/95 | 600 | 0.000289MG - 5.71MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| ORAL; TABLET, COATED | | 3 | | 04/20/76 | 600 | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 5 | | 05/20/83 | 600 | 0.12GM |
| ORAL; TABLET, SUSTAINED ACTION | | 3 | | 07/29/88 | 110 | 0.18MG - 2.33MG |
| SUBLINGUAL; TABLET | | 1 | | | | |
| DYE DC YELLOW #5 LAKE | | | | | | |
| ORAL; TABLET | | 8 | | 08/11/80 | 600 | 0.016MG - 2.69MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| DYE DC YELLOW #6 | | | | | | |
| ORAL; CAPSULE | | 3 | | 12/28/90 | 600 | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; TABLET | | 3 | | 01/12/73 | 600 | 0.005MG |
| ORAL-21; TABLET | | 1 | | | | |
| DYE DC YELLOW #6 LAKE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; TABLET | | 15 | | 11/02/87 | 600 | 0.27UGM |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| DYE FDC BLUE #1 | 002650182 | | | | | |
| DENTAL; PASTE | | 1 | | | | |
| DENTAL; SOLUTION | | 4 | | 12/28/95 | 600 | 0.00005% - 0.0015% |
| ORAL; CAPSULE | | 237 | | 10/18/95 | 600 | 5.0UGM |
| ORAL; CAPSULE, COATED PELLETS | | 2 | | 06/30/92 | 600 | |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 4 | | 10/05/95 | 180 | |
| ORAL; CAPSULE, HARD GELATIN | | 6 | | 03/27/95 | 600 | 3.708MG |
| ORAL; CAPSULE, SOFT GELATIN | | 3 | | 03/08/94 | 180 | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 28 | | 09/11/95 | 110 | 0.019MG - 0.9MG |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 04/23/79 | 600 | |
| ORAL; SOLUTION | | 5 | | 05/28/93 | 600 | 0.000075% - 0.75% |
| ORAL; SOLUTION, ELIXIR | | 2 | | 04/29/92 | 600 | |
| ORAL; SUSPENSION | | 2 | | 02/12/86 | 520 | 0.005% |
| ORAL; SYRUP | | 16 | | 12/23/88 | 600 | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE FDC BLUE #1 | 002650182 | | | | | |
| ORAL; TABLET | | 129 | | 06/29/95 | 600 | 5.0UGM - 11.4UGM |
| ORAL; TABLET, COATED | | 9 | | 02/11/82 | 120 | 0.0052MG - 0.0085MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 10 | | 10/31/91 | 180 | 0.51UGM |
| ORAL; TABLET, SUSTAINED ACTION | | 6 | | 11/08/93 | UNK | 0.03MG |
| ORAL-21; TABLET | | 3 | | 07/01/88 | 600 | 0.01MG - 0.05MG |
| ORAL-28; TABLET | | 6 | | 07/01/88 | 600 | 0.01MG - 0.05MG |
| RECTAL; SOLUTION | | 3 | | 05/28/93 | 600 | 0.000075% |
| SUBLINGUAL; TABLET | | 1 | | | | |
| TOPICAL; SHAMPOO | | 2 | | 08/27/90 | UNK | 0.0036% |
| TOPICAL; SUSPENSION, SHAMPOO | | 1 | | | | |
| TOPICAL; SWAB | | 1 | | | | |
| DYE FDC BLUE #1 ALUMINUM LAKE | | | | | | |
| ORAL; CAPSULE | | 12 | | 08/15/94 | 180 | |
| ORAL; CAPSULE, HARD GELATIN | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET | | 114 | | 12/29/95 | 600 | 0.001MG - 2.5MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| ORAL; TABLET, COATED | | 2 | | 04/20/76 | 600 | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 2 | | 05/15/90 | 600 | |
| ORAL; TABLET, FILM COATED | | 4 | | 05/30/95 | 600 | 0.1MG - 0.2MG |
| ORAL; TABLET, REPEAT ACTION | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 4 | | 07/29/88 | 110 | 0.009MG - 0.29MG |
| ORAL-28; TABLET | | 1 | | | | |
| DYE FDC BLUE #1 H.T. ALUMINUM LAKE | | | | | | |
| ORAL; TABLET | | 11 | | 08/31/88 | 600 | 0.012MG - 0.3MG |
| DYE FDC BLUE #1 LAKE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 35 | | 08/29/95 | 600 | 0.00364MG - 2.675MG |
| ORAL; TABLET, COATED | | 2 | | 04/08/81 | 600 | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL-28; TABLET | | 2 | | 12/30/94 | 510 | 0.045MG |
| DYE FDC BLUE #10 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| DYE FDC BLUE #2 | 000860220 | | | | | |
| BUCCAL; TABLET | | 1 | | | | |
| ORAL; CAPSULE | | 15 | | 10/18/95 | 600 | 0.012MG |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 1 | | | | |
| ORAL; CAPSULE, HARD GELATIN | | 2 | | 05/03/95 | 550 | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 3 | | 02/21/92 | 110 | 2.1UGM |
| ORAL; TABLET | | 75 | | 06/29/95 | 600 | 0.0015MG - 20.016MG |
| ORAL; TABLET, COATED | | 10 | | 02/25/92 | 600 | 24.12MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 11 | | 12/29/92 | 120 | 0.7MG |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE FDC BLUE #2 | 000860220 | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 5 | | 09/22/94 | 110 | |
| DYE FDC BLUE #2 LAKE | 012227859 | | | | | |
| ORAL; CAPSULE | | 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 | | 01/09/87 | 600 | 0.02MG |
| ORAL; TABLET, UNCOATED, TROCHE | | 1 | | | | |
| ORAL-21; TABLET | | 3 | | 07/03/92 | 510 | 0.1MG - 0.208MG |
| ORAL-28; TABLET | | 12 | | 11/17/95 | 510 | 0.0649MG - 0.208MG |
| DYE FDC GREEN #3 | 002353459 | | | | | |
| DENTAL; GEL | | 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 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| DYE FDC RED #27 LAKE | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; TABLET | | 3 | | 06/19/85 | 600 | 0.06MG |
| DYE FDC RED #28 | | | | | | |
| ORAL; CAPSULE | | 13 | | 03/29/91 | 600 | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| DYE FDC RED #3 | 016423680 | | | | | |
| ORAL; CAPSULE | | 84 | | 10/18/95 | 600 | 0.00036MG - 0.333MG |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 1 | | | | |
| ORAL; CAPSULE, HARD GELATIN | | 2 | | 03/28/67 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE FDC RED #3 | 016423680 | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 08/30/84 | 110 | |
| ORAL-28; TABLET | | 1 | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| DYE FDC RED #3 LAKE | | | | | | |
| ORAL; TABLET | | 13 | | 11/10/88 | 600 | 0.006MG - 1.2MG |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| DYE FDC RED #3-ALUMINUM LAKE | 012227780 | | | | | |
| ORAL; CAPSULE | | 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 | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; TABLET | | 4 | | 12/21/87 | 600 | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| DYE FDC RED #33 | | | | | | |
| ORAL; CAPSULE | | 4 | | 03/06/87 | 600 | 262.0MG |
| ORAL; SYRUP | | 5 | | 09/17/93 | 530 | 0.002% |
| DYE FDC RED #40 | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE FDC RED #40 | | | | | | |
| TOPICAL; SPONGE | | 2 | | 02/28/91 | 600 | 0.005% |
| DYE FDC RED #40 LAKE | | | | | | |
| ORAL; CAPLET | | 1 | | | | |
| ORAL; CAPSULE | | 9 | | 08/15/94 | 180 | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 2 | | 01/26/89 | 600 | 0.024MG - 0.05MG |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SOLUTION | | 2 | | 12/05/86 | 600 | |
| ORAL; SOLUTION, ELIXIR | | 2 | | 12/16/83 | 600 | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET | | 54 | | 10/20/95 | 600 | 0.01MG - 9.6MG |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 3 | | 07/29/92 | 600 | 0.368MG - 0.44MG |
| ORAL; TABLET, COATED | | 3 | | 04/08/81 | 600 | |
| ORAL; TABLET, FILM COATED | | 2 | | 12/20/91 | UNK | |
| ORAL; TABLET, SUSTAINED ACTION | | 4 | | 12/02/85 | 600 | 0.054MG |
| ORAL-28; TABLET | | 1 | | | | |
| SUBLINGUAL; TABLET | | 1 | | | | |
| DYE FDC RED #7 LAKE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 4 | | 02/27/91 | 600 | 0.06MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| DYE FDC YELLOW #10 | | | | | | |
| ORAL; CAPSULE | | 23 | | 10/18/95 | 600 | 0.2785MG |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SOLUTION | | 2 | | 12/05/88 | 600 | 5.0% |
| ORAL; SUSPENSION | | 2 | | 10/17/90 | 600 | 0.0015% |
| ORAL; SYRUP | | 4 | | 11/22/85 | 600 | |
| ORAL; TABLET | | 18 | | 03/25/94 | 600 | 0.07MG - 3.15MG |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 3 | | 02/02/87 | 600 | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| DYE FDC YELLOW #10 LAKE | | | | | | |
| ORAL; CAPSULE | | 3 | | 08/04/86 | 600 | |
| 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 | | | | | |
| BUCCAL/SUBLINGUAL; TABLET | | 1 | | | | |
| ORAL; CAPSULE | | 17 | | 08/23/84 | 600 | 0.06MG - 72.58MG |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 08/07/92 | 520 | 0.029MG - 0.9MG |
| ORAL; TABLET, REPEAT ACTION | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 9 | | 01/25/95 | 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| DYE RED COTOLENE-P | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| DYE SWEDISH ORANGE #2191 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| DYE TETRAROME ORANGE | | | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| DYE WHITE | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| DYE WHITE COATERIC YPA-6-7089 | | | | | | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 3 | | 05/15/90 | 600 | 0.002374GM |
| DYE WHITE COTOLENE-P | | | | | | |
| ORAL; TABLET | | 2 | | 07/15/86 | 600 | 10.35MG - 20.7MG |
| DYE WHITE TC-1032 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| DYE YELLOW | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| DYE YELLOW #10 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| DYE YELLOW #62 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| DYE YELLOW LB 9706 | | | | | | |
| ORAL; TABLET | | 2 | | 12/10/86 | 600 | 0.04MG - 0.27MG |
| DYE YELLOW OCHRE | 001345262 | | | | | |
| ORAL; TABLET | | 2 | | 10/15/86 | 180 | 0.024MG - 0.4MG |
| EDAMINE | | | | | | |
| 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 | 023411349 | | | | | |
| CAUDAL BLOCK; INJECTION | | 1 | | | | |
| EPIDURAL; INJECTION | | 2 | | 10/03/72 | 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 COUNT | LAST NDA | APPROVAL 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 | | 09/29/89 | 160 | 0.04% |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 05/04/77 | 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 | | | | |
| INTRAVENOUS; INJECTION | | 3 | | 06/18/93 | 120 | 1.2% |
| IV(INFUSION); INJECTION | | 6 | | 05/28/93 | 510 | 1.2% |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| ETHYLENE GLYCOL | 000107211 | | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 1 | | | | |
| ETHYLENE GLYCOL MONOETHYL ETHER | 000110805 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ETHYLENE VINYL ACETATE COPOLYMER | | | | | | |
| 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 | 000333186 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| ETHYLPARABEN | 000120478 | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| ETHYLPARABEN SODIUM | | | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 2 | | 12/30/86 | 150 | 0.24MG - 1.004MG |
| EUCALYPTOL | 000470826 | | | | | |
| DENTAL; SOLUTION | | 1 | | | | |
| EUDRAGIT E 100 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| EUDRAGIT E 30 D | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| EUDRAGIT L 30 D | | | | | | |
| 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 | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 4 | | 09/11/95 | 110 | 8.53MG - 36.173MG |
| EUDRAGIT RL 30 D | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| EUDRAGIT RS 30 D | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; TABLET, CONTROLLED RELEASE | | 1 | | | | |
| EXAMETAZIME | 100551631 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| FAT, EDIBLE | | | | | | |
| RECTAL; SUPPOSITORY | | 1 | | | | |
| FATTY ACID ESTERS, SATURATED | | | | | | |
| RECTAL; SUPPOSITORY | | 1 | | | | |
| FATTY ACID PENTAERYTHRIOL ESTER | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| FATTY ALCOHOL CITRATE | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| FATTY ALCOHOLS | | | | | | |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FERRIC OXIDE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; TABLET | | 7 | | 04/07/95 | 600 | 0.025MG - 4.56MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL-28; TABLET | | 2 | | 12/14/92 | 510 | |
| TOPICAL; LOTION | | 1 | | | | |
| 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 | | 7 | | 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 | | | | |
| FERROSOFERRIC 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 | | 02/27/57 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR | | | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, DISPERSIBLE | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| RECTAL; SOLUTION | | 2 | | 05/28/93 | 600 | |
| FLAVOR ANISE | | | | | | |
| ORAL; SOLUTION | | 2 | | 01/21/92 | 600 | |
| FLAVOR APPLE | 008047914 | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR APRICOT | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR APRICOT PEACH | | | | | | |
| ORAL; SYRUP | | 2 | | 11/22/85 | 600 | 0.05% |
| FLAVOR APRICOT 24829 | | | | | | |
| ORAL; SOLUTION | | 2 | | 12/05/88 | 600 | 0.3% - 1.0% |
| FLAVOR AROMALOK 182608 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR AROMALOK 262453 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR BANANA | 000123922 | | | | | |
| ORAL; GRANULE | | 2 | | 07/14/81 | 520 | |
| ORAL; POWDER, FOR RECONSTITUTION | | 4 | | 10/19/95 | 520 | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 3 | | 09/25/92 | 600 | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR BANANA SA84 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR BANANA 71507 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR BANANA 74546 | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR BERRY CITRUS BLEND 9621 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR BERRY CITRUS BLEND 9756 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR BERRY CREAM | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR BITTERNESS MODIFIER 15555 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR BLACK CHERRY | 008010433 | | | | | |
| ORAL; SYRUP | | 3 | | 07/22/92 | 600 | |
| FLAVOR BLACK CURRANT | | | | | | |
| ORAL; SYRUP | | 4 | | 04/18/84 | UNK | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR CUSTARD 52.940/A FIR | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR DF-119 | | | | | | |
| DENTAL; PASTE | | 1 | | | | |
| FLAVOR DF-1530 | | | | | | |
| DENTAL; GEL | | 1 | | | | |
| FLAVOR E-472 | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| FLAVOR ENHANCER | | | | | | |
| DENTAL; PASTE | | 1 | | | | |
| FLAVOR F-5397A | | | | | | |
| ORAL; CONCENTRATE | | 2 | | 04/27/83 | 600 | 0.008% - 8.0% |
| FLAVOR FELTON 6-R-9 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR FIG | | | | | | |
| ORAL; SOLUTION | | 2 | | 06/20/79 | 180 | 0.1% |
| RECTAL; SOLUTION | | 1 | | | | |
| FLAVOR FRITZSCHE | | | | | | |
| ORAL; SYRUP | | 2 | | 03/22/85 | 600 | |
| FLAVOR FRITZSCHE 21028-D | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR FRITZSCHE 75021 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR FRUIT GUM 912 | | | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR FRUIT MINT 75588 | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR FRUIT PUNCH | | | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR FRUIT PUNCH #28140 | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR FRUIT PUNCH 14761FM | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR FRUIT 01-10428 | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| FLAVOR FRUIT 84.6422 | | | | | | |
| BUCCAL; GUM, CHEWING | | 1 | | | | |
| FLAVOR FRUITS | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR GRAPE | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR GRAPE NECTOR PFC 8599 | | | | | | |
| ORAL; SYRUP | | 2 | | 01/17/89 | 600 | |
| FLAVOR GRAPE 13403873 | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR GRAPEFRUIT | | | | | | |
| ORAL; AEROSOL SPRAY | | 1 | | | | .27% |
| FLAVOR GRENADINE | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR GUARANA | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 03/27/78 | 600 | 0.12% - 0.16% |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR GUARANA FMC-15417 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR HAVERSTROO ZD 49284 | | | | | | |
| BUCCAL; GUM, CHEWING | | 1 | | | | |
| FLAVOR HERB ALPINE | | | | | | |
| DENTAL; SOLUTION | | 1 | | | | |
| FLAVOR KOLA | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR LEMON | 008020197 | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SOLUTION | | 2 | | 08/30/82 | 600 | 0.003% - 3.0% |
| ORAL; SUSPENSION | | 2 | | 06/03/59 | 120 | 0.116% |
| FLAVOR LEMON CREAM | | | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR LEMON LIME | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR LEMON MINT FRITZSCHE 54369 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR LEMON VANILLA | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| RECTAL; SOLUTION | | 1 | | | | |
| FLAVOR LEMON 812 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR LICORICE | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR LIME | | | | | | |
| ORAL; SOLUTION, ELIXIR | | 2 | | 04/07/89 | 600 | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR MAFCO-MAGNASWEET 180 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR MAQUE TREE 377(BUSH) | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR MCP LEMON DURAMONE 4409A | | | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR MCP LIME DURAMONE 6419 | | | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR MINT | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SOLUTION, ELIXIR | | 2 | | 04/07/89 | 600 | |
| ORAL; SUSPENSION | | 3 | | 10/10/85 | UNK | 0.206% |
| FLAVOR ORANGE | 008050326 | | | | | |
| ORAL; POWDER | | 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 | | 10 | | 03/30/94 | 600 | 0.000125% - 0.04% |
| ORAL; SYRUP | | 4 | | 06/10/87 | UNK | 0.4% |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| SUBLINGUAL; TABLET | | 1 | | | | |
| FLAVOR ORANGE #7679 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR ORANGE BANANA | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 04/18/91 | 600 | 0.2% - 0.4% |
| FLAVOR ORANGE BANANA WL-18093 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR ORANGE NATURAL & ARTIFICIAL | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR ORANGE TERPENELESS | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR ORANGE 13334 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR ORANGE-LEMON TERPENELESS | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR ORBIT SERENE 20340 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR PASSION FRUIT | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR PEACH | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR PEACH MINT FRITZSCHE 106109 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR PEACH PINEAPPLE | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SUSPENSION, SUSTAINED ACTION | | 1 | | | | |
| FLAVOR PEACH PINEAPPLE FMC 14258 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR PEACH 13503584 | | | | | | |
| ORAL; SOLUTION | | 2 | | 06/11/85 | UNK | |
| FLAVOR PEPPERMINT | | | | | | |
| 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 | | | | | | |
| ORAL; CONCENTRATE | | 2 | | 12/16/85 | 600 | 0.125% - 0.25% |
| FLAVOR PEPPERMINT 517 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR PEPPERMINT, NATURAL SPRAYLENE | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR PINEAPPLE | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 5 | | 04/28/95 | 600 | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 3 | | 03/30/94 | 600 | 0.01% - 0.02% |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR PINEAPPLE 182661 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR PINEAPPLE-COCONUT | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR RASPBERRY | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | | | |
| 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 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR RASPBERRY F-1784 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR RASPBERRY F-1840 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR RASPBERRY F-6887-S | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR RASPBERRY PFC-8407 | | | | | | |
| ORAL; CONCENTRATE | | 2 | | 12/16/85 | 600 | 0.25% - 0.5% |
| FLAVOR RASPBERRY POLAK 5000064 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR RASPBERRY 262085 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR RASPBERRY 28106 | | | | | | |
| ORAL; DROPS | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR RASPBERRY 954 | | | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR REFRACHESSMENT FD-8027D | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR RHODIA PHARMACEUTICAL #RF 451 | | | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| FLAVOR ROOT BEER | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR SHERRY | | | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| FLAVOR SPEARMINT | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| TOPICAL; OINTMENT | | 2 | | 08/17/81 | 600 | 0.3% - 1.0% |
| FLAVOR STRAWBERRY | | | | | | |
| 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 | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| FLAVOR STRAWBERRY F-5930-A | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR STRAWBERRY F21204 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR STRAWBERRY GUARANA 586.997/AP05.51 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR STRAWBERRY MICROSEAL | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR STRAWBERRY PFC-9626 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR STRAWBERRY WL-16650 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR STRAWBERRY 133.5655 | | | | | | |
| ORAL; GRANULE | | 1 | | | | |
| FLAVOR STRAWBERRY 14953 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR STRAWBERRY 52312/AP | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 05/23/88 | 600 | 0.09334% - 93.34% |
| FLAVOR STRAWBERRY 55058 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR STRAWBERRY 5951 | | | | | | |
| ORAL; DROPS | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR STRAWBERRY 9843 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR SWEET | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR SWEET TONE 28837 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR TANGERINE | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR TANGERINE FRITZSCHE 51465 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR TETRAROME | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR TPF 135 | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR TPF 143 | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR TROPICAL FRUIT PUNCH N&A 50432 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR TUTTI FRUTTI | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 08/14/80 | 600 | 0.06% |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR TUTTI FRUTTI 24093FM | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR TUTTI FRUTTI 51.880/AP05.51 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLAVOR VANILLA | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| FLAVOR VANILLA | | | | | | |
| RECTAL; SOLUTION | | 1 | | | | |
| TOPICAL; PASTE | | 1 | | | | |
| FLAVOR VANILLA BANANA | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| FLAVOR VANILLA CREME | | | | | | |
| ORAL; SOLUTION | | 2 | | 12/03/86 | 600 | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR VERALOCK BUBBLE GUM | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| FLAVOR WILD CHERRY | | | | | | |
| 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 | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 02/13/87 | 600 | 0.05% |
| FLAVOR WILD CHERRY PFC-14783 | | | | | | |
| ORAL; SYRUP | | 2 | | 12/22/88 | 600 | |
| FLAVOR WILDCHERRY 7598 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| FLAVOR WINTERGREEN | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| FLAVOR WINTERGREEN PFC 8421 | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLAVOR 57000 IU | | | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 08/07/81 | 520 | |
| FLAVOR 57820/A | | | | | | |
| ORAL; POWDER | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| FLORASYNTH | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| FLOUR | | | | | | |
| 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 | | | | | | |
| INHALATION; AEROSOL, METERED | | 1 | | | | |
| FORMALDEHYDE SOLUTION | 008006073 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| FRAGRANCE BOUQUET 10328 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| GELUCIRE 33/01 | | | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| GENTISIC ACID | 000490799 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| GENTISIC ACID ETHANOLAMIDE | | | | | | |
| IV(INFUSION); INJECTION | | 2 | | 08/08/85 | 510 | 1.0% |
| GINGER FLUIDEXTRACT | | | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| GLUCEPTATE SODIUM | 013007857 | | | | | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| GLUCONOLACTONE | 000090802 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; SOLUTION | | 2 | | 12/24/84 | 520 | 0.25% |
| TOPICAL; SPONGE | | 1 | | | | |
| GLUCOSE, LIQUID | 008027563 | | | | | |
| ORAL; PASTILLE | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 6 | | 04/18/84 | UNK | 0.275% - 62.0% |
| GLUCURONIC ACID | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| GLUTAMIC ACID HYDROCHLORIDE | 000138158 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| GLUTAMIC ACID, DL- | 000617652 | | | | | |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| GLUTEN | 008002800 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| GLYCERIN | 000056815 | | | | | |
| BUCCAL; GUM, CHEWING | | 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 | | 05/18/78 | 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 COUNT | LAST NDA | APPROVAL 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 | | 11/17/95 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| GLYCERYL OLEATE/PROPYLENE GLYCOL | | | | | | |
| TOPICAL; CREAM, AUGMENTED | | 1 | | | | |
| GLYCERYL PALMITATE | 001330730 | | | | | |
| RECTAL; SUPPOSITORY | | 2 | | 04/30/73 | 120 | |
| GLYCERYL RICINOLEATE | 001323382 | | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 4 | | 01/10/91 | 600 | 1.0% - 2.0% |
| GLYCERYL STEARATE | 031566311 | | | | | |
| OPHTHALMIC; SUSPENSION | | 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 | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| GLYCERYL STEARATE-STEARAMIDOETHYL DIETHYLAMINE | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| GLYCERYL STEARATE/PEG-100 STEARATE | | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 04/01/94 | UNK | 5.0% |
| TOPICAL; LOTION | | 2 | | 11/26/85 | 600 | 1.42% |
| GLYCERYL STEARATE/PEG-40 STEARATE | | | | | | |
| RECTAL; SUPPOSITORY | | 4 | | 02/27/95 | 600 | 15.0MG - 35.0MG |
| GLYCINE | 000056406 | | | | | |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION, LYOPHILI | | 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 | | 11/1/95 | 510 | |
| GLYCOL STEARATE | 000111604 | | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 1 | | | | |
| GLYCYRRHIZA | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| GLYCYRRHIZIN, AMMONIATED | 001407030 | | | | | |
| ORAL; GRANULE | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| GUANIDINE HYDROCHLORIDE | 000050011 | | | | | |
| INTRAVENOUS; INJECTION | | 2 | | 02/23/76 | 160 | 0.04% |
| GUAR GUM | 009000300 | | | | | |
| BUCCAL/SUBLINGUAL; TABLET | | 1 | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 2 | | 04/18/91 | 600 | 0.2% |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; TABLET | | 8 | | 12/01/86 | 600 | 1.296MG - 12.0MG |
| ORAL; TABLET, FILM COATED | | 4 | | 01/06/78 | 110 | 6.0MG - 35.4MG |
| ORAL; TABLET, SUSTAINED ACTION | | 3 | | 06/10/83 | UNK | 4.0MG - 5.04MG |
| TOPICAL; LOTION | | 1 | | | | |
| VAGINAL; TABLET | | 1 | | | | |
| GUM BASE, CHEWING | | | | | | |
| BUCCAL; GUM, CHEWING | | 2 | | 06/08/92 | UNK | |
| ORAL; TABLET | | 1 | | | | |
| GUM ROSIN | 008050100 | | | | | |
| ORAL; TABLET, REPEAT ACTION | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 4 | | 11/14/94 | UNK | 9.0MG |
| GUM, NATURAL | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| HERBACOL | 006365839 | | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| HEXYLENE GLYCOL | 000107415 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; OINTMENT | | 2 | | 04/30/87 | UNK | 12.0% |
| HIGH FRUCTOSE CORN SYRUP | | | | | | |
| ORAL; SUSPENSION, SUSTAINED ACTION | | 1 | | | | |
| HISTIDINE | 000071001 | | | | | |
| INTRAVENOUS; SUSPENSION, INJECTION | | 1 | | | | |
| HYDROCARBON GEL, PLASTICIZED | 008049658 | | | | | |
| DENTAL; PASTE | | 1 | | | | |
| OPHTHALMIC; OINTMENT | | 1 | | | | |
| TOPICAL; OINTMENT | | 4 | | 10/29/82 | UNK | |
| HYDROCHLORIC ACID | 007647010 | | | | | |
| CAUDAL BLOCK; INJECTION | | 15 | | 10/13/87 | 600 | 1.414% - 2.827% |
| DENTAL; SOLUTION | | 1 | | | | |
| EPIDURAL; INJECTION | | 31 | | 10/30/92 | UNK | |
| IM - IV - SC; INJECTION | | 50 | | 12/29/93 | 600 | |
| IM - IV; INJECTION | | 113 | | 12/27/94 | 600 | 0.00022% |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 11 | | 10/30/95 | 600 | |
| IM - IV; SOLUTION, INJECTION | | 3 | | 03/05/90 | 600 | |
| IM - SC; INJECTION | | 10 | | 01/23/85 | 510 | |
| IM - SC; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| INHALATION; AEROSOL, METERED | | 3 | | 09/03/92 | 510 | 0.7% - 1.72% |
| INHALATION; SOLUTION | | 23 | | 07/28/95 | 600 | |
| INTERSTITIAL; INJECTION | | 1 | | | | |
| INTRA-ARTICULAR; INJECTION | | 12 | | 11/05/81 | 600 | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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, LYOPHILI | | 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 | | 08/19/92 | 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 | | 01/22/92 | 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 COUNT | LAST NDA | APPROVAL 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 | | 07/22/86 | 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 | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | 0.58GM |
| 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 | | 03/30/89 | UNK | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| HYDROXYPROPYL METHYLCELLULOSE 2906 | 009004653 | | | | | |
| OPHTHALMIC; SOLUTION | | 2 | | 07/29/94 | 600 | 0.5% |
| ORAL; GRANULE, ENTERIC COATED | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| HYDROXYPROPYL METHYLCELLULOSE 2910 | 009004653 | | | | | |
| OPHTHALMIC; SOLUTION | | 3 | | 09/23/93 | UNK | 0.5% |
| OPHTHALMIC; SUSPENSION | | 3 | | 05/09/89 | 600 | 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 | 1.77MG - 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 | 5.8MG - 60.0MG |
| ORAL; TABLET, SUSTAINED ACTION | | 11 | | 11/18/94 | UNK | 5.7MG - 144.0MG |
| ORAL-28; TABLET | | 1 | | | | |
| IMIDAZOLIDINYL UREA | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| IMIDUREA | 039236469 | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 06/17/94 | UNK | 0.2% - 0.3% |
| TOPICAL; SHAMPOO | | 1 | | | | |
| INK BLACK | | | | | | |
| 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 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| INK BLACK A-10509 | | | | | | |
| ORAL; CAPSULE | | 3 | | 06/11/87 | 600 | |
| INK BLACK A-1057 | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | -- -- | | |
| INK BLACK IMPRINTING FGE-1386 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| INK BLUE BLACK A-9371 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| INK EDIBLE | | | | | | |
| ORAL; CAPSULE | | 11 | | 03/02/92 | 600 | |
| ORAL; CAPSULE, SOFT GELATIN | | 2 | | 12/30/86 | 150 | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 5 | | 02/28/92 | 600 | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| INK EDIBLE BLACK | | | | | | |
| ORAL; CAPSULE | | 7 | | 03/25/94 | UNK | |
| ORAL; TABLET | | 4 | | 02/16/88 | 600 | |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 01/09/87 | 600 | 1.0MG |
| ORAL-28; TABLET | | 1 | | | | |
| INK EDIBLE GRAY | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| INK EDIBLE RED | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| INK EDIBLE RED A-8032 | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 07/13/87 | UNK | |
| INK EDIBLE WHITE | | | | | | |
| ORAL; CAPSULE | | 3 | | 03/25/94 | UNK | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| INK FINE BLACK 2202C | | | | | | |
| ORAL; TABLET | | 2 | | 02/22/85 | 600 | 0.0007ML - 0.0011ML |
| INK FINE BLACK 2212 | | | | | | |
| ORAL; TABLET | | 3 | | 09/25/84 | 600 | |
| INK GREEN A-10454 | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| INK LIGHT REDWOOD | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| INK PINK IMPRINTING SB-1003 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| INK RED A-8032 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| INK RED S-1-9005 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| INK WHITE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |
| INK WHITE A-8154 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| INK WHITE 21-K | | | | | | |
| ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GEL | | 1 | | | | |
| INVERT SUGAR | 008013170 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; SYRUP | | 4 | | 06/07/85 | 600 | |
| IODINE | 007553562 | | | | | |
| INTRA-ARTERIAL; INJECTION | | 2 | | 08/29/74 | 160 | 28.2% - 37.0% |
| INTRA-ARTICULAR; INJECTION | | 1 | | | | |
| INTRACARDIAC; INJECTION | | 1 | | | | |
| INTRADISCAL; INJECTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | | | |
| ISOOCTYLACRYLATE | | | | | | |
| TOPICAL; TAPE | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| ISOPROPYL ALCOHOL | 000067630 | | | | | |
| ORAL; TABLET | | 3 | | 09/10/87 | 520 | |
| 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 COUNT | LAST NDA | APPROVAL 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 | 600 | 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 | | 10/01/84 | 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| LACTOSE | 000063423 | | | | | |
| INTRAVENOUS; INJECTION | | 5 | | 04/13/89 | 600 | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 2 | | 03/31/89 | 600 | 0.1% - 2.5% |
| 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 | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION, LYOPHILI | | 1 | | | | |
| ORAL; CAPSULE | | 7 | | 09/29/95 | 600 | 18.0MG - 360.0MG |
| ORAL; TABLET | | 35 | | 11/22/95 | 600 | 12.5MG - 370.0MG |
| ORAL; TABLET, ENTERIC COATED PARTICLES | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 2 | | 05/24/95 | 600 | 92.04MG - 260.0MG |
| LACTOSE MONOHYDRATE, ALPHA | 005989811 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| LACTOSE, ANHYDROUS | 000063423 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 15 | | 11/30/95 | 600 | 7.5MG - 415.8MG |
| ORAL; TABLET, COATED | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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, LYOPHILI | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| LAURETH SULFATE | | | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| LAURETH 23 | | | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| LAURETH 4 | 009002920 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| LAURIC DIETHANOLAMIDE | 000120401 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 2 | | 01/10/91 | 600 | |
| LAURIC MYRISTIC DIETHANOLAMIDE | | | | | | |
| TOPICAL; EMULSION | | 1 | | | | |
| LAURYL SULFATE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| LECITHIN | 008002435 | | | | | |
| INHALATION; AEROSOL, METERED | | 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% |
| LECITHIN, HYDROGENATED SOY | | | | | | |
| INTRAVENOUS; SUSPENSION, INJECTION | | 1 | | | | |
| LECITHIN, SOY BEAN | 008030760 | | | | | |
| INHALATION; AEROSOL, METERED | | 1 | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 2 | | 12/15/86 | 530 | 4.0MG - 20.0MG |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| LEMON OIL | 008008568 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| TOPICAL; GEL | | 1 | | | | |
| LEVOMENTHOL | 002216515 | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| LIDOFENIN | 059160291 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| LIME OIL | 008008262 | | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| LIMONENE, DL- | 000138863 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| LINEAR ALCOHOL ETHYLENE OXIDE ADDUCT | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| LUBRITAB | | | | | | |
| ORAL; TABLET | | 2 | | 12/22/82 | 600 | 3.45MG - 10.0MG |
| LYSINE | 000056871 | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| MAGNESIUM ALUMINUM SILICATE | 001327431 | | | | | |
| ORAL; DROPS | | 1 | | | | |
| ORAL; GRANULE | | 3 | | 12/18/80 | 600 | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 26 | | 05/30/94 | 600 | 0.15% - 2.0% |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET | | 2 | | 11/03/78 | 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 | | | | | |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 1 | | | | |
| ORAL; TABLET | | 8 | | 02/21/95 | 600 | 5.37MG - 250.0MG |
| ORAL; TABLET, COATED | | 2 | | 09/30/59 | 120 | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| MAGNESIUM CHLORIDE | 007791186 | | | | | |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| INTRAOCULAR; SOLUTION | | 2 | | 04/28/95 | 600 | 0.03% |
| INTRAPERITONEAL; SOLUTION | | 1 | | | | |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION | | 2 | | 09/22/93 | UNK | |
| MAGNESIUM HYDROXIDE | 001309428 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 2 | | 10/09/91 | 530 | 12.44MG - 450.0MG |
| MAGNESIUM NITRATE | 010377603 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| MAGNESIUM OXIDE | 001309484 | | | | | |
| ORAL; CAPSULE | | 2 | | 04/25/88 | 600 | 10.0MG |
| ORAL; TABLET | | 15 | | 02/09/94 | 510 | 5.0MG - 20.0MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 04/23/85 | 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 | | 12/15/93 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| MALEIC ACID | 000110167 | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET | | 2 | | 06/28/78 | 510 | 2.0MG |
| MALIC ACID | 006915157 | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| MALIC ACID, DL- | | | | | | |
| ORAL; SOLUTION | | 2 | | 04/27/88 | 510 | |
| ORAL; TABLET | | 1 | | | | |
| MALTODEXTRIN | | | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; TABLET | | 4 | | 11/05/92 | 600 | |
| MALTOL | 000118718 | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; SOLUTION | | 4 | | 10/31/93 | 600 | |
| ORAL; SYRUP | | 1 | | | | |
| MALTOLDEXTRIN | 009050366 | | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| MALTOSE | 000069794 | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| MANNITOL | 000069658 | | | | | |
| IM - IV; INJECTION | | 2 | | 04/22/70 | 510 | |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| IM - SC; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| INTRAMUSCULAR; INJECTION | | 3 | | 01/21/94 | 510 | |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION | | 2 | | 10/17/85 | 510 | |
| INTRAVENOUS; INJECTION | | 12 | | 12/24/91 | 510 | 10.0% |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 12 | | 11/29/95 | 600 | 100.0MG |
| IV(INFUSION); INJECTION | | 5 | | 02/16/89 | 600 | 2.0% - 10.0% |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 11 | | 09/20/95 | 180 | 37.0MG - 1500.0MG |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION | | 3 | | 09/22/93 | UNK | |
| OPHTHALMIC; SOLUTION | | 4 | | 11/04/93 | UNK | 4.05% - 4.6% |
| OPHTHALMIC; SUSPENSION | | 2 | | 12/30/94 | UNK | 4.5% |
| ORAL; CAPSULE | | 4 | | 03/30/89 | 600 | 65.6MG - 283.1MG |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| MANNOSE, D- | 000530267 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| MEBROFENIN | 078266065 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| MEDICAL ANTIFOAM EMULSION C | | | | | | |
| ORAL; SUSPENSION | | 6 | | 03/18/87 | 600 | 0.08% |
| ORAL; TABLET | | 1 | | | | |
| MEDICAL ANTIFORM A-F EMULSION | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| MEDRONATE DISODIUM | 025681894 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| MEDRONIC ACID | 001984152 | | | | | |
| INTRAVENOUS; INJECTION | | 3 | | 02/17/81 | 160 | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| MEGLUMINE | 006284408 | | | | | |
| INTRA-ARTERIAL; INJECTION | | 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 | 000089781 | | | | | |
| DENTAL; SOLUTION | | 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 | 013478983 | | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| METHACRYLIC ACID COPOLYMER | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| METHANESULFONIC ACID | 000075752 | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| METHIONINE | 000063683 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| METHYL ACRYLATE - METHYL METHACRYLATE | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| METHYL BORONIC ACID | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| METHYL GLUCETH-120 DIOLEATE | | | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| METHYL HYDROXYETHYL CELLULOSE | | | | | | |
| ORAL; TABLET | | 2 | | 06/02/87 | 600 | 12.0MG - 24.0MG |
| METHYL LAURATE | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| METHYL SALICYLATE | 000119368 | | | | | |
| TOPICAL; GEL | | 1 | | | | |
| METHYL STEARATE | 000112618 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| METHYLATED SPIRITS | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| METHYLCELLULOSE | 009004675 | | | | | |
| INTRAMUSCULAR; INJECTION | | 2 | | 07/07/83 | 600 | 0.03% |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 3 | | 08/29/72 | 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 | | 04/24/85 | UNK | 0.2% - 1.5% |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| METHYLCELLULOSE 400 | | | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| METHYLCHLOROISOTHIAZOLINONE | 026172554 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| METHYLENE BLUE | 000061734 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| METHYLISOTHIAZOLINONE | 002682204 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| METHYLPARABEN | 000099763 | | | | | |
| CAUDAL BLOCK; INJECTION | | 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 | | 05/18/78 | 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 COUNT | LAST NDA | APPROVAL 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 | | 2 | | 05/27/94 | 600 | 0.18% |
| RECTAL; SOLUTION | | 1 | | | | |
| RECTAL; SUSPENSION | | 2 | | 11/17/86 | 600 | |
| SOFT TISSUE; INJECTION | | 2 | | 06/19/80 | 600 | 0.15% |
| SUBCUTANEOUS; INJECTION | | 9 | | 12/19/91 | UNK | 0.1% - 0.15% |
| TOPICAL; EMULSION, AEROSOL FOAM | | 2 | | 12/19/79 | 600 | 0.108% |
| TOPICAL; EMULSION, CREAM | | 65 | | 10/31/94 | 600 | 0.018% - 0.3% |
| TOPICAL; GEL | | 2 | | 11/22/88 | UNK | 0.08% - 0.3% |
| TOPICAL; GEL, JELLY | | 2 | | 04/29/93 | 600 | 0.007% |
| TOPICAL; LOTION | | 15 | | 12/07/92 | UNK | 0.08% - 0.3% |
| TOPICAL; OINTMENT | | 12 | | 09/30/94 | 600 | 0.02% - 0.4% |
| TOPICAL; SHAMPOO | | 1 | | | | |
| TOPICAL; SOLUTION | | 4 | | 04/03/85 | 600 | 0.1% |
| TOPICAL; SUSPENSION, SHAMPOO | | 1 | | | | |
| URETERAL; SOLUTION | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 12 | | 12/21/95 | 520 | 0.1% - 0.18% |
| VAGINAL; GEL | | 1 | | | | |
| VAGINAL; SUPPOSITORY | | 1 | | | | |
| METHYLPARABEN SODIUM | 005026620 | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 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 | | 13 | | 09/26/89 | 120 | 0.0002ML - 85.0ML |
| ORAL; TABLET, COATED | | 1 | | | | |
| 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 | | 64 | | 06/13/95 | 600 | 3.0% - 40.0% |
| TOPICAL; LOTION | | 9 | | 12/30/88 | UNK | 1.0% - 16.0% |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| MINERAL OIL | | | | | | |
| TOPICAL; OIL | 008012951 | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| TOPICAL; PASTE | | 44 | | 03/23/95 | 600 | 0.1% - 95.0% |
| TOPICAL; SUPPOSITORY | | 1 | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 2 | | 04/26/93 | 520 | |
| VAGINAL; EMULSION, CREAM | | 3 | | 10/28/94 | 510 | 2.31MG - 12.4MG |
| VAGINAL; SUPPOSITORY | | 8 | | 12/21/95 | 520 | 2.0% - 7.0% |
| MINERAL OIL, LIGHT | | 1 | | | | |
| 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 | | 1 | | | | |
| TOPICAL; LOTION | | 8 | | 09/28/92 | 600 | 3.0% - 20.0% |
| TOPICAL; OINTMENT | | 5 | | 01/24/92 | 600 | 7.0% - 16.0% |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 15 | | 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% - 0.169% |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| N-(CARBAMOYL-METHOXYPOLYETHYLENE GLYCOL 2000)-1,2-DISTEAROYL | | | | | | |
| INTRAVENOUS; SUSPENSION, INJECTION | | 1 | | | | |
| N-DECYL-METHYL SULFOXIDE | | | | | | |
| TOPICAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| N-2-HYDROXYETHYLPIPERAZINE N'-2'-ETHANESULPHONIC ACID | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| N-3-CHLOROALLYL-METHENAMINE CHLORIDE | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| N,N-BIS(2-HYDROXYETHYL)STEARAMIDE | | | | | | |
| ORAL; TABLET | 000093823 | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| N,N-DIMETHYL LAURAMINE OXIDE | | | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| N,N-DIMETHYLACETAMIDE | | | | | | |
| 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 | | | | | | |
| ORAL; AEROSOL | | 1 | | | | |
| NIOXIME | | | | | | |
| INTRAVENOUS; INJECTION | 000492999 | 1 | | | | |
| NIPASTAT | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| NITRIC ACID | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| OPHTHALMIC; SOLUTION | 026027383 | 3 | | 06/25/86 | 600 | 70.2MG - 157.5MG |
| NONOXYNOL-15 | | | | | | |
| TOPICAL; SOLUTION | 026027383 | 1 | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| NUTMEG OIL, EXPRESSED | | | | | | |
| ORAL; SOLUTION, ELIXIR | 008007123 | 1 | | | | |
| OATMEAL | | | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| OCTADECENE-1/MALEIC ACID COPOLYMER | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| OCTOXYNOL | | | | | | |
| TOPICAL; SOLUTION | 009002931 | 1 | | | | |
| | | 1 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| OCTOXYNOL-1 | 009002931 | | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| OCTOXYNOL-40 | | | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| OCTOXYNOL-9 | 009002931 | | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| TOPICAL; SPONGE | | 2 | | 01/07/87 | 520 | |
| OCTYLDODECANOL | 005333426 | | | | | |
| TOPICAL; EMULSION, CREAM | | 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 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| OLEIC ACID | 000112801 | | | | | |
| INHALATION; AEROSOL, METERED | | 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 | | 11/14/94 | UNK | 2.0MG |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| OLETH-10/OLETH-5 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| OLETH-2 | | | | | | |
| TOPICAL; OIL | | 1 | | | | |
| OLEYL OLEATE | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| OLIVE OIL | 008001250 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| OPACOAT NA2203 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPACODE S-1-13001 (ORANGE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPACODE S-1-1666 (RED) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION, COATED | | 1 | | | | |
| OPACODE S-1-4157 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| OPACODE S-1-4160 (BLUE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPACODE S-1-4172 (BLUE) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| OPADRY YS-1-11051 (GREEN) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| OPADRY YS-1-1107 (GREEN) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-1252 (PINK) | | | | | | |
| ORAL; TABLET, FILM COATED | | 2 | | 03/26/93 | 110 | 3.5MG - 4.5MG |
| OPADRY YS-1-12525-A (YELLOW) | | | | | | |
| ORAL; TABLET, CONTROLLED RELEASE | | 1 | | | | |
| OPADRY YS-1-12529 (YELLOW) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-1288 (PINK) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-1298 (PINK) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-14416 | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-14518A (PINK) | | | | | | |
| ORAL; TABLET, CONTROLLED RELEASE | | 1 | | | | |
| OPADRY YS-1-1510 (PINK) | | | | | | |
| ORAL; TABLET | | 3 | | 05/15/90 | 600 | 4.2MG |
| OPADRY YS-1-1528 (PINK) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-1724 (RED) | | | | | | |
| ORAL; TABLET | | 2 | | 11/23/87 | 600 | 9.221MG - 18.566MG |
| OPADRY YS-1-18034 (WHITE) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-1846 (RED) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-1847 (RED) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-2013 (YELLOW) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-2065 | | | | | | |
| ORAL; CAPLET | | 1 | | | | |
| OPADRY YS-1-2074 (YELLOW) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-2122 (YELLOW) | | | | | | |
| ORAL; TABLET | | 2 | | 09/24/86 | 600 | |
| OPADRY YS-1-2134 (YELLOW) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-2136 (YELLOW) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-2167 (YELLOW) | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| OPADRY YS-1-4215 | | | | | | |
| ORAL; TABLET | | 2 | | 01/11/94 | UNK | |
| OPADRY YS-1-4216 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-4221 (BLUE) | | | | | | |
| ORAL; TABLET | | 2 | | 12/10/86 | 600 | |
| OPADRY YS-1-4229 (BLUE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-4236 (BLUE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-4245 (BLUE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-4298 (BLUE) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-4710 | | | | | | |
| ORAL; TABLET | | 3 | | 05/19/86 | 600 | 4.0MG |
| OPADRY YS-1-6275 (ORANGE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-6312 (YELLOW) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-6357 (YELLOW) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-7002 (WHITE) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-7003 (WHITE) | | | | | | |
| 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) | | | | | | |
| 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) | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION, COATED | | 1 | | | | |
| OPADRY YS-1-7444G (WHITE) | | | | | | |
| ORAL; TABLET, COATED | | 2 | | 05/17/94 | 600 | 11.0MG - 22.0MG |
| OPADRY YS-1-7507 (GREY) | | | | | | |
| ORAL; TABLET | | 2 | | 11/23/87 | 600 | 9.443MG - 19.057MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-7552 (GREY) | | | | | | |
| ORAL; TABLET | | 2 | | 03/09/87 | 600 | 7.3MG |
| OPADRY YS-1-7706G (WHITE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| OPADRY YS-1-8325 (BEIGE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-8345G (BEIGE) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-8619 (ORANGE) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-1-89193 (CLEAR) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-1-9012 (BROWN) | | | | | | |
| ORAL; TABLET | | 4 | | 12/08/87 | 600 | 12.6MG |
| OPADRY YS-2-7013 (CLEAR) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 2 | | 09/14/95 | 110 | .7MG<br>0.6MG - 1.2MG |
| OPADRY YS-2-7063 (WHITE) | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | 04/26/94 | 510 | 19.0MG - 24.0MG |
| OPADRY YS-3-7011 (CLEAR) | | | | | | |
| ORAL; TABLET | | 24 | | 05/15/90 | 600 | 0.5MG - 17.2MG |
| OPADRY YS-3-7031 (CLEAR) | | | | | | |
| ORAL; TABLET | | 5 | | 09/12/86 | 600 | 2.5MG - 8.0MG |
| OPADRY YS-3-7413 (CLEAR) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-5-1296 (PINK) | | | | | | |
| ORAL; TABLET | | 2 | | 03/25/94 | 600 | 5.775MG - 11.55MG |
| OPADRY YS-5-2170 (YELLOW) | | | | | | |
| ORAL; TABLET | | 2 | | 02/16/88 | 600 | 6.112MG |
| OPADRY YS-5-2370 (ORANGE) | | | | | | |
| ORAL; TABLET | | 4 | | 09/16/83 | 600 | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPADRY YS-5-7042 (CLEAR) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPADRY YS-5-7068 | | | | | | |
| ORAL; TABLET | | 4 | | 09/29/87 | 600 | |
| OPAGLOS CLEAR | | | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| OPAGLOS GS 2-0310 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPALUX AS 1537 (PINK) | | | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| OPALUX AS 1589 (PINK) | | | | | | |
| ORAL; TABLET, COATED | | 4 | | 11/19/82 | 600 | 0.022MG - 0.07MG |
| OPALUX AS 2006 (YELLOW) | | | | | | |
| ORAL; TABLET | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| OPASPRAY L-3306 (GREEN) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPASPRAY L-7000 (WHITE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPASPRAY M-1-7118 (WHITE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPASPRAY M-1-7111-B | | | | | | |
| ORAL; TABLET | | 4 | | 12/16/92 | 120 | 0.92MG - 26.67MG |
| OPASPRAY M-1-7120 (WHITE) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPASPRAY M-1-7301 (WHITE) | | | | | | |
| ORAL; TABLET, COATED | | 1 | | | | .2MG |
| OPASPRAY M-1-8429 (YELLOW) | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| OPASPRAY WD-1270 (PINK) | | | | | | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| OPASPRAY 3-1820 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPASPRAY 3-1830 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPATINT DD-13009 (ORANGE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| OPATINT DD-1800 (WHITE) | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORANGE FLOWER OIL | 008022977 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORANGE JUICE | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORANGE JUICE,SYNTHETIC | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORANGE OIL | 008008579 | | | | | |
| ORAL; GRANULE, EFFERVESCENT | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SOLUTION, ELIXIR | | 7 | | 12/17/82 | 600 | 0.024% |
| ORAL; SYRUP | | 1 | | | | |
| ORANGE OIL, TERPENELESS | | | | | | |
| ORAL; SUSPENSION | | 2 | | 11/18/82 | 600 | |
| ORAL; SYRUP | | 1 | | | | |
| OXIDRONATE SODIUM | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| OXYQUINOLINE | 000148243 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| PALM KERNEL OIL | 008023798 | | | | | |
| RECTAL; SUPPOSITORY | | 1 | | | | |

## INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| PALM KERNEL OIL, HYDROGENATED | 068990829 | | | | | |
| RECTAL; SUPPOSITORY | | 1 | | | | |
| PALM OIL - SOYBEAN OIL, HYDROGENATED | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| PALM OIL, HYDROGENATED | 008033292 | | | | | |
| RECTAL; SUPPOSITORY | | 1 | | | | |
| PALMITAMINE OXIDE | 007128918 | | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| PARABENS | | | | | | |
| 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 | 008002742 | | | | | |
| ORAL; TABLET | | 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 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| PEANUT OIL | 008002037 | | | | | |
| INTRAMUSCULAR; INJECTION | | 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 | 009000695 | | | | | |
| DENTAL; PASTE | | 3 | | 07/06/87 | 600 | 16.6% - 16.7% |
| TOPICAL; PASTE | | 1 | | | | |
| PEG VEGETABLE OIL | 008051352 | | | | | |
| IM - SC; INJECTION | | 1 | | | | |
| PEGLICOL-5-OLEATE | | | | | | |
| 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 | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| PENTAERYTHRITOL COCOATE | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| PENTETATE CALCIUM TRISODIUM | 012111249 | | | | | |
| INTRAVENOUS; INJECTION | | 2 | | 11/16/76 | 160 | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| PENTETATE PENTASODIUM | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| PENTETIC ACID | 000067436 | | | | | |
| INTRATHECAL; INJECTABLE | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 2 | | 12/19/90 | 160 | 0.015% |
| PEPPERMINT | | | | | | |
| DENTAL; SOLUTION | | 1 | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| PEPPERMINT OIL | 008006904 | | | | | |
| DENTAL; SOLUTION | | 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 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| PERFUME GD 5604 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| PERFUME TANA 90/42 SCBA | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| PERFUMES | | | | | | |
| 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 | 008009038 | | | | | |
| OPHTHALMIC; OINTMENT | | 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% |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 03/31/95 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| PHENYLETHYL ALCOHOL | 000060128 | | | | | |
| NASAL; SPRAY, METERED | | 3 | | 10/19/94 | UNK | 0.25% |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| OPHTHALMIC; SUSPENSION | | 1 | | | | |
| OTIC; SOLUTION | | 1 | | | | |
| PHENYLMERCURIC ACETATE | 000062384 | | | | | |
| OPHTHALMIC; OINTMENT | | 3 | | 12/03/86 | 600 | 0.0008% |
| PHENYLMERCURIC NITRATE | 000055685 | | | | | |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| PHOSPHATE BUFFER | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| PHOSPHOLIPID | | | | | | |
| IV(INFUSION); INJECTION | | 3 | | 12/30/93 | 510 | 1.2% |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION, LYOPHILI | | 1 | | | | |
| PHOSPHORIC ACID | 007664382 | | | | | |
| 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 | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| PINEAPPLE | | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| PIPERAZINE | 000110850 | | | | | |
| ORAL; TABLET | | 4 | | 09/23/93 | 600 | |
| PIPERAZINE HEXAHYDRATE | 000142632 | | | | | |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| PLASTIBASE-50W | | | | | | |
| TOPICAL; OINTMENT | | 3 | | 06/15/88 | 600 | 99.95% |
| PLUSWEET | | | | | | |
| SUBLINGUAL; TABLET | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 COUNT | LAST NDA | APPROVAL 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 | | 05/19/92 | 110 | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 4 | | 11/30/95 | 600 | 4.5MG - 4.63MG |
| ORAL; TABLET, ENTERIC COATED PARTICLES | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 49 | | 12/08/95 | UNK | 0.013MG - 3.17MG |
| ORAL; TABLET, SUSTAINED ACTION | | 15 | | 09/22/94 | 110 | 1.3MG - 3.46MG |
| ORAL-21; TABLET | | 1 | | | | |
| 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% |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| POLYETHYLENE GLYCOL 1450 | | | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| POLYETHYLENE GLYCOL 1500 | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| POLYETHYLENE GLYCOL 1540 | | | | | | |
| DENTAL; GEL | | 1 | | | | |
| DENTAL; PASTE | | 1 | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| RECTAL; SUPPOSITORY | | 1 | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| POLYETHYLENE GLYCOL 200 | | | | | | |
| ORAL; CAPSULE | | 2 | | 01/27/81 | 120 | |
| TOPICAL; OINTMENT | | 2 | | 06/03/77 | 600 | 39.0% |
| POLYETHYLENE GLYCOL 20000 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL-28; TABLET | | 2 | | 11/17/95 | 510 | 0.3MG |
| POLYETHYLENE GLYCOL 300 | 025322683 | | | | | |
| 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 | | | | | | |
| INTRA-ARTICULAR; INJECTION | | 2 | | 09/05/61 | UNK | 3.0% |
| INTRALESIONAL; INJECTION | | 1 | | | | |
| INTRAMUSCULAR; INJECTION | | 3 | | 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 | | 10/22/87 | 520 | 0.6MG - 10.0MG |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 4 | | 08/01/94 | 110 | 0.6MG - 1.25MG |
| RECTAL; SUPPOSITORY | | 3 | | 08/31/92 | 600 | |
| SOFT TISSUE; INJECTION | | 1 | | | | |
| TOPICAL; OINTMENT | | 6 | | 12/31/87 | 520 | 22.0% - 39.0% |
| VAGINAL; SUPPOSITORY | | 1 | | | | |
| POLYETHYLENE GLYCOL 3500 | | | | | | |
| ORAL; TABLET, FILM COATED | | 2 | | 10/03/90 | 600 | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| POLYETHYLENE GLYCOL 40 SORBITAN DIISOSTEARATE | | | | | | |
| DENTAL; SOLUTION | | 3 | | 12/28/95 | 600 | 0.08% - 2.265% |
| POLYETHYLENE GLYCOL 400 | 009004960 | | | | | |
| IM - IV; INJECTION | | 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 | 320.41MG - 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 | | | | | | |
| 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 | 600 | |
| 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 | 006790096 | | | | | |
| INTRAVENOUS; SOLUTION, INJECTION | | 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 COUNT | LAST NDA | APPROVAL 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 | | | | |
| POLYGLACTIN | 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 COUNT | LAST NDA | APPROVAL 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| POLYOXYL 20 STEARATE | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| POLYOXYL 35 CASTOR OIL | 061791126 | | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| IV(INFUSION); SOLUTION, INJECTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| POLYOXYL 40 CASTOR OIL | | | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| POLYOXYL 40 HYDROGENATED CASTOR OIL | 061788850 | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| POLYOXYL 40 STEARATE | 009004993 | | | | | |
| DENTAL; SOLUTION | | 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 | | 02/21/92 | 520 | 0.8MG - 8.48MG |
| OTIC; SUSPENSION | | 1 | | | | |
| 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 | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| POLYOXYL 60 CASTOR OIL | | | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| POLYOXYL 75 LANOLIN | | | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| POLYOXYL 8 STEARATE | 009004993 | | | | | |
| TOPICAL; EMULSION, CREAM | | 3 | | 10/08/85 | 600 | 1.0% - 8.0% |
| POLYOXYPROPYLENE 15 STEARYL ETHER | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| POLYOXYPROPYLENE 26 OLEATE | | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 06/13/88 | 600 | 1.5% - 4.0% |
| POLYPROPYLENE | 009003070 | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 2 | | 10/10/84 | 110 | 4.5MG - 13.5MG |
| POLYPROPYLENE GLYCOL | 009003150 | | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| ORAL; TABLET | | 2 | | 12/28/88 | 110 | 1.26MG |
| POLYSACCHARIDE | | | | | | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| POLYSILOXANE | 009014135 | | | | | |
| ORAL; CAPSULE | | 4 | | 04/21/87 | 600 | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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, LYOPHILI | | 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 | | 05/31/95 | 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 | | 11/06/85 | 600 | 0.01% - 5.0% |
| RECTAL; ENEMA | | 2 | | 05/27/94 | 600 | |
| RECTAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| RECTAL; SOLUTION | | 2 | | 12/19/77 | 160 | |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 09/15/93 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| POLYVINYL ACETATE PHTHALATE | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| POLYVINYL ALCOHOL | 009002895 | | | | | |
| OPHTHALMIC; SOLUTION | | 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 | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| POLYVINYLPYRIDINE | 000100936 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| POLYVINYLPYRROLIDONE ETHYLCELLULOSE | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| POPPY SEED OIL | 008002117 | | | | | |
| INTRALYMPHATIC; OIL | | 1 | | | | |
| INTRAUTERINE; OIL | | 1 | | | | |
| POTASSIUM ACETATE | 000127082 | | | | | |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| RECTAL; ENEMA | | 1 | | | | |
| POTASSIUM CARBONATE | 000584087 | | | | | |
| ORAL; CAPSULE | | 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 | 007447407 | | | | | |
| CAUDAL BLOCK; INJECTION | | 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 | 006100056 | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| POTASSIUM HYDROXIDE | 001310583 | | | | | |
| INTRAVENOUS; INJECTION | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| POTASSIUM METABISULFITE | 004429429 | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 5 | | 11/18/85 | 510 | |
| NERVE BLOCK; INJECTION | | 2 | | 01/22/85 | 600 | 0.12% |
| OTIC; SOLUTION | | 4 | | 12/29/95 | 600 | 0.1% |
| OTIC; SUSPENSION | | 1 | | | | |
| RECTAL; ENEMA | | 1 | | | | |
| POTASSIUM PHOSPHATE, DIBASIC | 007758114 | | | | | |
| INTRAVENOUS; SOLUTION | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 2 | | 03/18/87 | 600 | |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |
| SUBCUTANEOUS; INJECTION | | 1 | | | | |
| POTASSIUM PHOSPHATE, MONOBASIC | 007778770 | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| INTRA-ARTICULAR; INJECTION | | 1 | | | | |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 2 | | 11/16/76 | 160 | 0.076% |
| NERVE BLOCK; INJECTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 6 | | 05/04/94 | 600 | 0.03402% - 0.2% |
| OPHTHALMIC; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 3 | | 10/31/95 | 600 | 0.095% |
| ORAL; TABLET, DISPERSIBLE | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| OTIC; SOLUTION | | 1 | | | | |
| POTASSIUM POLACRILIN | | | | | | |
| ORAL; TABLET | | 2 | | 05/15/90 | 600 | 24.0MG |
| POTASSIUM SORBATE | 000590001 | | | | | |
| ORAL; CAPSULE | | 5 | | 09/30/86 | UNK | |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SOLUTION | | 3 | | 12/03/86 | 600 | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 3 | | 11/10/83 | 600 | |
| ORAL; TABLET | | 3 | | 11/05/92 | 600 | 0.8MG |
| TOPICAL; EMULSION, CREAM | | 10 | | 02/01/89 | 600 | 0.095% - 0.15% |
| TOPICAL; LOTION | | 2 | | 06/05/78 | 600 | 0.1% |
| POVIDONE | 009003398 | | | | | |
| INTRAMUSCULAR; INJECTION | | 7 | | 07/07/83 | 600 | 0.03% - 0.9% |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| POVIDONE | 009003398 | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 26 | | 03/16/94 | 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 |
| POVIDONE K25 | 0 | | | | | |
| ORAL; TABLET | | 2 | | 06/29/95 | 600 | 0.44MG - 52.0MG |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| POVIDONE K29-32 | | | | | | |
| 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 | | | | |
| POVIDONE K30 | | | | | | |
| 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 |
| POVIDONE K90 | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| POVIDONE K90 | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| PROMALGEN TYPE G | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| PROMULGEN D | | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| PROMULGEN G | 009009614 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 2 | | 11/26/85 | 600 | 2.16% |
| TOPICAL; SHAMPOO | | 1 | | | | |
| PROPANE | 000074986 | | | | | |
| TOPICAL; AEROSOL SPRAY | | 1 | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| PROPENYL GUAETHOL | 000094860 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| PROPYL GALLATE | 000121799 | | | | | |
| INTRAMUSCULAR; INJECTION | | 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 | 000108327 | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| PROPYLENE GLYCOL | 000057556 | | | | | |
| IM - IV; INJECTION | | 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 | | 05/16/95 | 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 | | 07/17/95 | 600 | 5.0% - 7.0% |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 05/25/95 | 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 | | 09/29/87 | 600 | 2.0% - 10.0% |
| RECTAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| RECTAL; SUSPENSION | | 2 | | 11/17/86 | 600 | |
| TOPICAL; AEROSOL | | 1 | | | | |
| TOPICAL; CREAM, AUGMENTED | | 1 | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 3 | | 12/19/79 | 600 | 5.3/6% |
| 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 | | 05/31/95 | 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 | 25.0% |
| 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% |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| PROPYLPARABEN | 000094133 | | | | | |
| INTRA-ARTICULAR; INJECTION | | 3 | | 06/19/80 | 600 | 0.02% |
| INTRABURSAL; INJECTION | | 1 | | | | |
| INTRALESIONAL; INJECTION | | 3 | | 06/19/80 | 600 | 0.02% |
| INTRAMUSCULAR; INJECTION | | 27 | | 02/25/93 | 600 | 0.01% - 0.02% |
| INTRASYNOVIAL; INJECTION | | 2 | | 03/01/77 | UNK | 0.02% |
| INTRAVENOUS; INJECTION | | 16 | | 12/20/91 | UNK | 0.005% - 0.03% |
| IV - SC; INJECTION | | 2 | | 12/05/85 | 180 | 0.015% - 0.02% |
| IV(INFUSION); INJECTION | | 19 | | 03/25/94 | 160 | 0.0005% - 0.056% |
| NASAL; SOLUTION | | 2 | | 05/18/70 | 510 | 0.017% |
| NERVE BLOCK; INJECTION | | 2 | | 03/06/72 | 600 | 0.005% - 0.015% |
| OPHTHALMIC; OINTMENT | | 8 | | 08/31/95 | 600 | 0.01% |
| OPHTHALMIC; SOLUTION | | 9 | | 10/18/88 | 600 | 0.01% - 0.015% |
| OPHTHALMIC; SUSPENSION | | 2 | | 12/28/82 | 600 | 0.01% |
| ORAL; CAPSULE | | 79 | | 12/20/95 | 520 | 0.0246MG - 0.188MG |
| 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 | 0.05MG - 0.081MG |
| ORAL; CAPSULE, SUSTAINED ACTION | | 8 | | 04/25/95 | UNK | |
| ORAL; CONCENTRATE | | 23 | | 09/28/93 | 600 | 0.004% - 0.03% |
| ORAL; POWDER, FOR RECONSTITUTION | | 5 | | 12/31/91 | 520 | 0.01% - 0.08% |
| ORAL; SOLUTION | | 42 | | 11/17/95 | 530 | 0.01% - 20.0% |
| ORAL; SOLUTION, ELIXIR | | 10 | | 10/27/92 | 600 | 0.02% |
| ORAL; SUSPENSION | | 41 | | 09/15/95 | 180 | 0.01% - 0.05% |
| ORAL; SUSPENSION, SUSTAINED ACTION | | 1 | | | | |
| ORAL; SYRUP | | 39 | | 07/17/95 | 600 | 0.0085% - 0.02% |
| ORAL; TABLET | | 19 | | 03/30/94 | 600 | 0.0045MG - 0.14MG |
| ORAL; TABLET, COATED | | 11 | | 04/08/81 | 600 | 0.002MG |
| ORAL; TABLET, FILM COATED | | 2 | | 12/28/87 | 520 | 0.02MG - 0.04MG |
| ORAL; TABLET, SUSTAINED ACTION | | 3 | | 05/22/87 | UNK | 0.12MG |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| PROPYLPARABEN | 000094133 | | | | | |
| URETERAL; SOLUTION | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 11 | | 12/21/95 | 520 | 0.02% - 0.1% |
| VAGINAL; GEL | | 1 | | | | |
| VAGINAL; SUPPOSITORY | | 1 | | | | |
| PROPYLPARABEN SODIUM | 035285699 | | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 2 | | 12/30/86 | 150 | 0.12MG - 0.28MG |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| PROSWEET | | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 1 | | | | |
| PROSWEET 604 | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| PROTAMINE SULFATE | 009009658 | | | | | |
| IM - SC; INJECTION | | 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 | 009015547 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| RA-2397 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| RA-3011 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| ROSIN | 008050097 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |
| ORAL; TABLET, REPEAT ACTION | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| SACCHARIN | 000081072 | | | | | |
| INHALATION; AEROSOL, METERED | | 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 | 006381915 | | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |

# INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | | | |
| SATIALGINE 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 COUNT | LAST NDA | APPROVAL 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 | | 11/18/83 | 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 | 0.007GM |
| 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 | 0.72MG - 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 | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM ACETATE | 006131904 | | | | | |
| IV(INFUSION); SOLUTION, INJECTION | | 2 | | 12/28/95 | 110 | 0.0189% - 1.7% |
| NASAL; SOLUTION | | 1 | | | | |
| OPHTHALMIC; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 4 | | 06/17/91 | UNK | 0.07% - 0.272% |
| OPHTHALMIC; SUSPENSION | | 1 | | | | |
| ORAL; CONCENTRATE | | 2 | | 12/16/85 | 600 | 0.125% |
| ORAL; SOLUTION | | 2 | | 09/30/74 | 160 | 0.16% |
| OTIC; SOLUTION | | 7 | | 10/31/94 | 600 | 0.015% |
| OTIC; SOLUTION, DROPS | | 1 | | | | |
| OTIC; SUSPENSION | | 2 | | 12/14/66 | 520 | 0.042% - 1.905% |
| SUBCUTANEOUS; INJECTION | | 6 | | 06/25/91 | 510 | 0.14% - 0.2% |
| SODIUM ACETATE, ANHYDROUS | 000127093 | | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| IM - SC; INJECTION | | 1 | | | | |
| INTRAMUSCULAR; INJECTION | | 2 | | 11/26/82 | 600 | 0.471% |
| INTRAVENOUS; SOLUTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| SUBCUTANEOUS; INJECTION | | 3 | | 09/30/85 | 510 | 0.16% |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| SODIUM ACID PYROPHOSPHATE | 007758169 | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| SODIUM ALGINATE | 009005383 | | | | | |
| ORAL; SUSPENSION | | 3 | | 01/26/84 | 600 | 0.14% - 0.7% |
| ORAL; TABLET | | 3 | | 05/01/84 | 510 | 20.0MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 07/31/92 | 600 | 320.0MG |
| SODIUM ALKYL SULFATE | 008036542 | | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 1 | | | | |
| SODIUM AMINOBENZOATE | 000555066 | | | | | |
| ORAL; CAPSULE | | 3 | | 02/18/75 | 600 | 0.0011MG - 0.0017MG |
| ORAL; TABLET | | 1 | | | | |
| SODIUM ASCORBATE | 000134032 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| SODIUM BENZOATE | 000532321 | | | | | |
| DENTAL; GEL | | 1 | | | | |
| DENTAL; PASTE | | 1 | | | | |
| IM - IV; INJECTION | | 15 | | 01/29/93 | 600 | 4.775% - 5.0% |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| ORAL; CAPSULE | | 13 | | 08/19/91 | 600 | 0.3MG |
| ORAL; CAPSULE, HARD GELATIN | | 1 | | | | |
| ORAL; CONCENTRATE | | 11 | | 01/30/92 | 600 | 0.05% - 0.2% |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUN BENZOATE | 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 | | 01/22/87 | 600 | |
| ORAL-21; TABLET | | 1 | | | | |
| ORAL-28; TABLET | | 2 | | 12/30/94 | 510 | |
| RECTAL; ENEMA | | 1 | | | | |
| TOPICAL; EMULSION | | 1 | | | | |
| SODIUM BICARBONATE | 000144558 | | | | | |
| BUCCAL; GUM, CHEWING | | 1 | | | | |
| IM - IV; INJECTION | | 1 | | | | |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 5 | | 07/26/93 | 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 |
| SODIUM BISULFATE | 007681381 | | | | | |
| IM - IV; INJECTION | | 5 | | 03/28/83 | 600 | 0.1% - 0.75% |
| INHALATION; SOLUTION | | 1 | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| SODIUM BISULFITE | 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 COUNT | LAST NDA | APPROVAL 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 | | 02/26/86 | 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 | 0.32% - 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 | | 12/07/92 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM CARBONATE | 000497198 | | | | | |
| IV(INFUSION); INJECTION | | 3 | | 10/31/93 | 600 | |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 2 | | 09/10/85 | 600 | |
| NERVE BLOCK; INJECTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 11 | | 10/31/95 | 600 | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 3 | | 02/27/85 | 600 | 1.0MG - 6.0MG |
| ORAL; TABLET | | 3 | | 07/21/95 | 600 | 10.4MG - 87.5MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| RECTAL; SUSPENSION | | 1 | | | | |
| SODIUM CARBONATE HYDRATE | 005968116 | | | | | |
| INTRA-ARTERIAL; INJECTION | | 1 | | | | |
| INTRACARDIAC; INJECTION | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 1 | | | | |
| SODIUM CARRAGENATE | | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| SODIUM CELLULOSE | | | | | | |
| ORAL; CAPSULE | | 2 | | 10/15/80 | UNK | 10.0MG - 150.0MG |
| SODIUM CHLORATE | 007775099 | | | | | |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| NERVE BLOCK; INJECTION | | 1 | | | | |
| SODIUM CHLORIDE | 007647145 | | | | | |
| CAUDAL BLOCK; INJECTION | | 16 | | 10/13/87 | 600 | 0.21% - 0.855% |
| DENTAL; INJECTION | | 2 | | 10/10/84 | 600 | 0.4% - 0.6% |
| EPIDURAL; INJECTION | | 38 | | 02/26/93 | 600 | 0.0006% - 0.9% |
| IM - IV - SC; INJECTION | | 47 | | 04/11/89 | 600 | 0.1% - 0.9% |
| IM - IV; INJECTION | | 60 | | 12/27/94 | 600 | 0.08% - 1.2% |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 8 | | 12/27/91 | 600 | |
| IM - SC; INJECTION | | 17 | | 04/14/95 | 600 | 0.25% - 9.0% |
| INHALATION; SOLUTION | | 34 | | 09/26/95 | 600 | 0.02% - 0.9% |
| INTRA-ARTERIAL; INJECTION | | 8 | | 08/23/91 | 600 | 0.26% - 1.2% |
| INTRA-ARTICULAR; INJECTION | | 21 | | 05/24/82 | 600 | 0.2% - 0.9% |
| INTRABURSAL; INJECTION | | 5 | | 02/13/74 | 600 | 0.66% - 0.9% |
| INTRACARDIAC; INJECTION | | 4 | | 01/06/76 | 600 | 0.45% - 0.7% |
| INTRACAVITARY; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| INTRADERMAL; INJECTION | | 4 | | 10/16/87 | UNK | 0.2% - 0.7% |
| INTRALESIONAL; INJECTION | | 7 | | 10/16/87 | UNK | 0.2% - 0.9% |
| INTRAMUSCULAR; INJECTION | | 47 | | 01/27/95 | 600 | 0.0017% - 0.9% |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| INTRAMUSCULAR; SOLUTION, INJECTION | | 2 | | 04/17/95 | UNK | 0.85% - 0.9% |
| INTRAOCULAR; SOLUTION | | 2 | | 04/28/95 | 600 | 0.64% |
| INTRAPERITONEAL; POWDER, FOR INJECTION SOLUTION | | 4 | | 07/03/86 | 600 | |
| INTRAPERITONEAL; SOLUTION | | 1 | | | | |
| INTRAPLEURAL; POWDER, FOR INJECTION SOLUTION | | 4 | | 07/03/86 | 600 | |
| INTRASYNOVIAL; INJECTION | | 10 | | 11/05/81 | 600 | 0.2% - 0.9% |
| INTRATHECAL; INJECTABLE | | 3 | | 06/17/92 | 120 | 0.85% - 0.9% |
| INTRATHECAL; INJECTION | | 17 | | 10/30/92 | UNK | 0.26% - 0.9% |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 07/28/95 | 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 | | 07/28/95 | 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 | | 1 | | | | |
| NASAL; SOLUTION | | 5 | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM CHLORIDE INJECTION, BACTERIOSTATIC | | | | | | |
| 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 |

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

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM HYDROXIDE | 001310732 | | | | | |
| EPIDURAL; INJECTION | | 34 | | 10/30/92 | UNK | |
| IM - IV - SC; INJECTION | | 27 | | 12/28/83 | 600 | |
| 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 | | 08/25/91 | 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, LYOPHILI | | 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 | | 08/19/92 | 160 | |
| INTRAPLEURAL; INJECTION | | 1 | | | | |
| INTRASYNOVIAL; INJECTION | | 9 | | 02/17/84 | 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 | | 07/08/88 | 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | 600 | 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 | 600 | 0.45MG |
| ORAL; TABLET, COATED | | 1 | | | | |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 2 | | 10/14/94 | UNK | |
| OTIC; SOLUTION | | 4 | | 12/29/95 | 600 | 0.049% - 0.56% |
| PERFUSION/CARDIAC; SOLUTION | | 1 | | | | |
| PERIDURAL; INJECTION | | 1 | | | | |
| RECTAL; ENEMA | | 1 | | | | |
| RECTAL; SOLUTION | | 8 | | 10/24/95 | 160 | |
| RETROBULBAR; INJECTION | | 1 | | | | |
| SOFT TISSUE; INJECTION | | 10 | | 05/24/82 | 600 | |
| SPINAL; INJECTION | | 6 | | 12/11/87 | 600 | |
| SUBCONJUNCTIVAL; INJECTION | | 1 | | | | |
| SUBCUTANEOUS; INJECTION | | 19 | | 03/31/94 | 510 | |
| SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| TOPICAL; CREAM, AUGMENTED | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 32 | | 09/20/95 | UNK | 0.00668% - 0.283% |
| TOPICAL; GEL | | 6 | | 04/29/94 | UNK | |
| TOPICAL; GEL, JELLY | | 3 | | 04/29/93 | 600 | |
| TOPICAL; LOTION | | 25 | | 09/30/94 | 600 | 0.004% - 2.8% |
| TOPICAL; LOTION, AUGMENTED | | 1 | | | | |
| TOPICAL; OINTMENT | | 2 | | 02/03/87 | 600 | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| TOPICAL; SOLUTION | | 18 | | 12/15/95 | 600 | 0.0213% |
| TOPICAL; SPONGE | | 3 | | 01/07/87 | 520 | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| URETERAL; SOLUTION | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 2 | | 12/21/95 | 520 | 0.18813% |
| VAGINAL; GEL | | 1 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM HYPOCHLORITE | 007681529 | | | | | |
| IV(INFUSION); INJECTION | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| SODIUM IODIDE | 007681825 | | | | | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| SODIUM L-CYSTEINATE HYDROCHLORIDE | | | | | | |
| INTRADISCAL; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| SODIUM L-LACTATE | 000867561 | | | | | |
| EPIDURAL; INJECTION | | 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 | 000072173 | | | | | |
| CAUDAL BLOCK; INJECTION | | 1 | | | | |
| IM - IV - SC; INJECTION | | 1 | | | | |
| INTRACARDIAC; INJECTION | | 1 | | | | |
| INTRAPERITONEAL; SOLUTION | | 1 | | | | |
| NERVE BLOCK; INJECTION | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| SODIUM LAURETH SULFATE | 001335724 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| SODIUM LAURETH-5 SULFATE | 009004824 | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| SODIUM LAUROYL SARCOSINATE | 000137166 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| SODIUM LAURYL SULFATE | 000151213 | | | | | |
| BUCCAL/SUBLINGUAL; TABLET | | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM LAURYL SULFATE | 000151213 | | | | | |
| ORAL; TABLET, FILM COATED | | 21 | | 05/30/95 | 600 | 0.13MG - 4.5MG |
| ORAL; TABLET, SUSTAINED ACTION | | 5 | | 11/25/91 | 600 | 1.76MG - 15.0MG |
| SUBLINGUAL; TABLET | | 3 | | 07/07/80 | 600 | 0.01MG - 0.02MG |
| TOPICAL; EMULSION, CREAM | | 12 | | 09/28/92 | 600 | 0.1% - 2.5% |
| TOPICAL; LOTION | | 5 | | 01/24/92 | 600 | 0.25% |
| TOPICAL; OINTMENT | | 2 | | 08/08/83 | UNK | 0.15% - 1.0% |
| TOPICAL; SPONGE | | 1 | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 2 | | 01/10/91 | 600 | |
| VAGINAL; EMULSION, CREAM | | 3 | | 09/19/85 | 600 | 0.3% - 0.333% |
| SODIUM LAURYL SULFOACETATE | 001847581 | | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| SODIUM METABISULFITE | 007757746 | | | | | |
| CAUDAL BLOCK; INJECTION | | 4 | | 10/13/87 | 600 | 0.05% - 0.183% |
| EPIDURAL; INJECTION | | 6 | | 02/26/93 | 600 | 0.05% - 0.183% |
| IM - IV - SC; INJECTION | | 5 | | 04/10/89 | 600 | 0.1% - 0.15% |
| IM - IV; INJECTION | | 37 | | 12/14/95 | 600 | 0.0007% - 0.66% |
| INHALATION; SOLUTION | | 1 | | | | |
| INTRACARDIAC; INJECTION | | 2 | | 11/15/74 | 600 | 0.09% - 0.1% |
| INTRAMUSCULAR; INJECTION | | 16 | | 06/26/95 | 600 | 0.0025% - 0.66% |
| INTRAVENOUS; INJECTION | | 22 | | 05/18/92 | 600 | 0.01% - 0.32% |
| INTRAVENOUS; SOLUTION, INJECTION | | 1 | | | | |
| IONTOPHORESIS; SOLUTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 48 | | 06/26/95 | 600 | 0.024% - 1.0% |
| NERVE BLOCK; INJECTION | | 33 | | 02/26/93 | 600 | 0.05% - 0.5% |
| OPHTHALMIC; SOLUTION | | 6 | | 03/06/86 | 600 | 0.01% - 0.3% |
| OPHTHALMIC; SUSPENSION | | 1 | | | | |
| ORAL; CAPSULE | | 2 | | 08/30/91 | 600 | 0.36MG |
| ORAL; CONCENTRATE | | 3 | | 12/10/81 | 600 | 0.1% - 0.2% |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 1 | | | | |
| ORAL; TABLET | | 6 | | 01/15/86 | 600 | 0.2MG - 4.1MG |
| SODIUM PHOSPHATE | 007632055 | | | | | |
| IM - IV; INJECTION | | 8 | | 07/22/82 | 600 | 0.3% - 1.0% |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 3 | | 05/28/81 | 600 | |
| IM - IV; SOLUTION, INJECTION | | 1 | | | | |
| INTRA-ARTICULAR; INJECTION | | 2 | | 02/27/79 | 600 | 0.58% - 1.0% |
| INTRADERMAL; INJECTION | | 3 | | 02/08/77 | 510 | 0.25% |
| INTRALESIONAL; INJECTION | | 1 | | | | |
| INTRAMUSCULAR; INJECTION | | 4 | | 07/07/83 | 600 | 0.29% - 0.58% |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| INTRAVENOUS; INJECTION | | 4 | | 12/24/87 | 150 | 0.16% |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| IV(INFUSION); INJECTION | | 7 | | 12/20/84 | 600 | 0.18% |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 2 | | 10/04/62 | UNK | |
| NASAL; SOLUTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 8 | | 03/31/95 | UNK | 0.075% - 0.81% |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 10/31/95 | 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, LYOPHILI | | 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 | 600 | 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 | 600 | 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 | 600 | 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 COUNT | LAST NDA | APPROVAL 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 | | 01/07/87 | 520 | |
| 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, LYOPHILI | | 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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, LYOPHILI | | 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 | | 02/10/89 | 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 |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM STARCH GLYCOLATE | 009063381 | | | | | |
| ORAL; TABLET, COATED | | 27 | | 06/23/95 | 600 | 1.2MG - 32.01MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 3 | | 06/18/85 | 520 | 10.0MG - 21.0MG |
| ORAL; TABLET, ENTERIC COATED PARTICLES | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 32 | | 12/27/95 | 150 | 1.5MG - 53.0MG |
| ORAL; TABLET, SUSTAINED ACTION | | 4 | | 08/19/91 | UNK | 0.75MG - 31.3MG |
| ORAL-21; TABLET | | 1 | | | | |
| ORAL-28; TABLET | | 4 | | 03/29/76 | 510 | |
| SUBLINGUAL; TABLET | | 5 | | 02/26/88 | 600 | 0.7MG - 2.0MG |
| SODIUM STEARYL FUMARATE | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; TABLET | | 10 | | 03/28/95 | 110 | 1.8MG - 6.0MG |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| SODIUM SUCCINATE | 000150903 | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| SODIUM SULFATE | 007727733 | | | | | |
| OPHTHALMIC; SOLUTION | | 2 | | 05/25/94 | 600 | 0.04% |
| OPHTHALMIC; SUSPENSION | | 1 | | | | |
| SODIUM SULFATE, ANHYDROUS | 007757826 | | | | | |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 2 | | 12/13/84 | 600 | 0.152% |
| ORAL; TABLET | | 1 | | | | |
| SODIUM SULFITE | 007757837 | | | | | |
| EPIDURAL; INJECTION | | 1 | | | | |
| IM - IV; INJECTION | | 16 | | 05/13/88 | 600 | 0.08% - 0.15% |
| INHALATION; SOLUTION | | 6 | | 09/16/83 | 600 | 0.025% |
| INTRA-ARTICULAR; INJECTION | | 3 | | 04/09/86 | 600 | 0.1% |
| INTRALESIONAL; INJECTION | | 1 | | | | |
| INTRAMUSCULAR; INJECTION | | 3 | | 04/15/88 | 600 | 0.05% - 0.1% |
| INTRAVENOUS; INJECTION | | 4 | | 11/06/91 | UNK | 0.15% - 0.2% |
| IV(INFUSION); INJECTION | | 2 | | 07/08/87 | 600 | 0.1% |
| ORAL; CONCENTRATE | | 3 | | 04/27/83 | 600 | 0.015% - 0.04993% |
| ORAL; SUSPENSION | | 1 | | | | |
| OTIC; SOLUTION | | 1 | | | | |
| SOFT TISSUE; INJECTION | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| SODIUM TARTRATE | 000868188 | | | | | |
| IM - IV; INJECTION | | 4 | | 08/29/89 | 600 | 1.2% |
| INTRAMUSCULAR; INJECTION | | 4 | | 12/05/88 | 600 | 0.475% - 1.2% |
| INTRAVENOUS; INJECTION | | 2 | | 06/15/90 | 160 | |
| IV(INFUSION); INJECTION | | 4 | | 08/29/89 | 600 | 1.2% |
| SODIUM THIOGLYCOLATE | 000367511 | | | | | |
| SUBCUTANEOUS; INJECTION | | 1 | | | | |
| SODIUM THIOSULFATE | 010102177 | | | | | |
| INTRAVENOUS; SOLUTION | | 1 | | | | |
| OPHTHALMIC; SOLUTION | | 9 | | 05/05/87 | 600 | 0.0902% - 0.31% |
| OPHTHALMIC; SUSPENSION | | 6 | | 09/29/89 | UNK | 0.1% - 0.32% |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SODIUM THIOSULFATE | 010102177 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; SOLUTION | | 4 | | 08/18/78 | 160 | 0.248% |
| ORAL; TABLET | | 1 | | | | |
| SODIUM THIOSULFATE, ANHYDROUS | 007772987 | | | | | |
| INTRAVENOUS; SOLUTION | | 3 | | 04/17/78 | 160 | |
| ORAL; SOLUTION | | 4 | | 04/17/78 | 160 | 0.2% |
| ORAL; TABLET | | 1 | | | | |
| SODIUM TRIMETAPHOSPHATE | 007785844 | | | | | |
| INTRAVENOUS; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| SOLULAN | 008042511 | | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| SORBIC ACID | 000110441 | | | | | |
| 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 | 600 | |
| 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 | | | | | |
| OPHTHALMIC; OINTMENT | | 1 | | | | |
| ORAL; GRANULE, EFFERVESCENT | | 1 | | | | |
| ORAL; SUSPENSION | | 3 | | 11/21/80 | 600 | |
| ORAL; SYRUP | | 1 | | | | |
| SORBITAN MONOOLEATE | 005938385 | | | | | |
| ORAL; TABLET | | 2 | | 10/31/91 | 520 | 1.0MG |
| 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 | | | | | |
| INTRAMUSCULAR; INJECTION | | 2 | | 12/23/75 | 520 | 0.05% |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; LOTION | | 6 | | 08/14/86 | 600 | 0.08005% - 0.45% |
| SORBITAN MONOSTEARATE | 001338416 | | | | | |
| TOPICAL; EMULSION, CREAM | | 54 | | 06/13/95 | 600 | 0.25% - 5.2% |
| TOPICAL; LOTION | | 6 | | 01/24/92 | 600 | 0.14% - 2.5% |
| TOPICAL; OINTMENT | | 1 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SORBITAN MONOSTEARATE | 001338416 | | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| TOPICAL; SUPPOSITORY | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 7 | | 12/21/95 | 520 | 2.0% |
| VAGINAL; SUPPOSITORY | | 1 | | | | |
| SORBITAN SESQUIOLEATE | 008007430 | | | | | |
| TOPICAL; OINTMENT | | 14 | | 03/31/95 | 600 | 0.5% - 2.0% |
| SORBITAN SOLUTION | | | | | | |
| ORAL; CONCENTRATE | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| SORBITAN TRIOLEATE | 005960065 | | | | | |
| INHALATION; AEROSOL, METERED | | 12 | | 12/30/92 | UNK | 0.5% |
| NASAL; AEROSOL, METERED | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |
| SORBITOL | 000050704 | | | | | |
| BUCCAL; GUM, CHEWING | | 2 | | 06/08/92 | UNK | |
| INTRA-ARTICULAR; INJECTION | | 2 | | 02/17/84 | 600 | 45.0% |
| INTRALESIONAL; INJECTION | | 2 | | 02/17/84 | 600 | 45.0% |
| INTRAMUSCULAR; INJECTION | | 1 | | | | |
| INTRASYNOVIAL; INJECTION | | 2 | | 02/17/84 | 600 | 45.0% |
| INTRAVENOUS; INJECTION | | 2 | | 08/18/95 | 110 | 6.8% - 7.14% |
| IV(INFUSION); INJECTION | | 1 | | | | |
| NASAL; SOLUTION | | 2 | | 05/18/70 | 510 | 2.5% |
| NASAL; SPRAY, METERED | | 1 | | | | |
| ORAL; CAPSULE | | 9 | | 07/30/93 | 600 | 51.1MG - 71.22MG |
| ORAL; CAPSULE, SOFT GELATIN | | 4 | | 03/08/94 | 180 | 66.82MG |
| ORAL; CONCENTRATE | | 8 | | 01/30/92 | 600 | 30.0% - 60.0% |
| ORAL; GRANULE, FOR RECONSTITUTION | | 1 | | | | |
| ORAL; SOLUTION | | 9 | | 10/31/95 | 600 | 35.0% |
| ORAL; SOLUTION, ELIXIR | | 2 | | 04/23/64 | UNK | |
| ORAL; SUSPENSION | | 8 | | 02/12/86 | 520 | 70.0% |
| ORAL; SYRUP | | 18 | | 09/17/93 | 530 | 5.0% - 72.0% |
| ORAL; TABLET | | 7 | | 11/01/85 | 600 | 0.004GM - 0.016GM |
| ORAL; TABLET, COATED | | 3 | | 03/15/62 | 120 | 6.48MG |
| ORAL; TABLET, FILM COATED | | 2 | | 08/10/82 | 520 | 2.5MG - 5.0MG |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| RECTAL; SUSPENSION | | 1 | | | | |
| SUBLINGUAL; TABLET | | 2 | | 08/11/81 | 600 | |
| TOPICAL; EMULSION, CREAM | | 8 | | 04/29/94 | 600 | 2.377% - 5.0% |
| TOPICAL; LOTION | | 1 | | | | |
| VAGINAL; TABLET | | 1 | | | | |
| SORBITOL SOLUTION | 003959533 | | | | | |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 11/17/86 | 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% |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 | | 04/28/88 | 600 | |
| 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 | | 04/06/83 | 180 | 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 |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| STARCH, POTATO | | | | | | |
| ORAL; TABLET | | 17 | | 09/06/95 | 510 | 12.0MG - 77.0MG |
| ORAL; TABLET, COATED | | 6 | | 02/25/92 | 600 | 11.88MG - 13.26MG |
| ORAL; TABLET, REPEAT ACTION | | 1 | | | | |
| STARCH, PREGELATINIZED | | | | | | |
| ORAL; CAPLET | | 1 | | | | |
| ORAL; CAPSULE | | 79 | | 10/18/95 | 600 | 2.7MG - 360.0MG |
| ORAL; CAPSULE, HARD GELATIN | | 4 | | 05/03/95 | 530 | 41.9MG - 81.0MG |
| ORAL; CAPSULE, SUSTAINED ACTION | | 2 | | 05/29/92 | 110 | 82.03MG - 141.75MG |
| ORAL; DROPS | | 1 | | | | 1.2% |
| 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 | | 06/28/85 | 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 | | | | | | |
| ORAL; CAPSULE | | 11 | | 06/28/91 | 600 | 50.0MG - 161.1MG |
| ORAL; TABLET | | 74 | | 12/29/95 | 600 | 1.8MG - 482.0MG |
| 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 M | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| STEARALKONIUM CHLORIDE | 000122190 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| STEARALKONIUM HECTORITE/PROPYLENE CARBONATE | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| STEARAMIDOETHYL DIETHYLAMINE | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 4 | | 06/09/86 | 600 | 0.5% - 0.8% |
| STEARETH | 009005009 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| STEARETH-10 | | | | | | |
| RECTAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| STEARETH-100 | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| STEARETH-2 | | | | | | |
| 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 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 09/04/92 | UNK | 2.25% - 3.0% |
| STEARIC ACID | 000057114 | | | | | |
| IMPLANTATION; PELLET | | 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 | | 06/29/93 | 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 | | 11/17/95 | 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 |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| STEARYL ALCOHOL | 000112925 | | | | | |
| ORAL; TABLET, CONTROLLED RELEASE | | 1 | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 2 | | 09/09/87 | 600 | 244.0MG |
| TOPICAL; EMULSION, CREAM | | 60 | | 06/13/95 | 600 | 1.0% - 30.0% |
| TOPICAL; LOTION | | 17 | | 09/30/92 | UNK | 0.2% - 4.0% |
| TOPICAL; OINTMENT | | 4 | | 08/08/83 | UNK | 0.00075% - 8.0% |
| VAGINAL; EMULSION, CREAM | | 5 | | 12/21/95 | 520 | 6.0% - 7.0% |
| STEARYL CITRATE | 001337333 | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| SUCCIMER | 000304552 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| SUCCINIC ACID | 000110156 | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| ORAL; CONCENTRATE | | 2 | | 10/31/93 | 600 | 0.2% |
| ORAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| SUCROSE | 000057501 | | | | | |
| BUCCAL/SUBLINGUAL; TABLET | | 1 | | | | |
| INTRAVENOUS; SUSPENSION, INJECTION | | 1 | | | | |
| ORAL; CAPSULE | | 22 | | 09/11/92 | 530 | 5.0MG - 413.655MG |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 56 | | 02/08/95 | UNK | 0.002MG - 236.1MG |
| ORAL; CONCENTRATE | | 9 | | 11/30/94 | 600 | 10.0% - 71.94% |
| ORAL; DROPS | | 3 | | 05/25/95 | UNK | 30.0% |
| ORAL; GRANULE | | 7 | | 06/15/88 | 600 | |
| ORAL; GRANULE FOR RECONSTITUTION, CR | | 1 | | | | |
| ORAL; GRANULE, FOR RECONSTITUTION | | 2 | | 12/23/93 | 520 | |
| ORAL; PASTILLE | | 1 | | | | |
| ORAL; POWDER | | 2 | | 12/05/88 | 510 | 0.006368% |
| ORAL; POWDER, FOR RECONSTITUTION | | 61 | | 12/20/95 | 520 | |
| ORAL; SOLUTION | | 13 | | 11/17/95 | 530 | 20.0% - 60.0% |
| ORAL; SOLUTION, ELIXIR | | 20 | | 04/29/93 | 600 | 12.5% - 29.75% |
| ORAL; SUSPENSION | | 42 | | 06/16/95 | UNK | 25.5% - 60.0% |
| ORAL; SUSPENSION, SUSTAINED ACTION | | 1 | | | | |
| ORAL; SYRUP | | 49 | | 10/28/94 | 600 | 23.9659% - 82.105% |
| ORAL; TABLET | | 159 | | 10/06/95 | UNK | 0.0325GM - 0.9GM |
| ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, | | 7 | | 09/11/95 | 600 | 1.2GM - 2.4GM |
| ORAL; TABLET, COATED | | 58 | | 02/25/92 | 600 | 2.0MG - 300.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 2 | | 06/23/81 | 600 | 4.99MG |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| ORAL; TABLET, REPEAT ACTION | | 2 | | 03/31/81 | UNK | 129.551MG |
| ORAL; TABLET, SUSTAINED ACTION | | 14 | | 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 | | | | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| SUCROSE POLYESTERS | | | | | | |
| TOPICAL; POWDER, FOR RECONSTITUTION | | 1 | | | | |
| SUCROSE STEARATE | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| SUCROSE SYRUP | | | | | | |
| ORAL; SOLUTION | | 2 | | 04/27/88 | 510 | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 3 | | 01/13/95 | 600 | |
| ORAL; TABLET | | 1 | | | | |
| SUGAR COMPRESSIBLE | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| ORAL; SYRUP | | 4 | | 01/04/85 | 600 | |
| SUGAR NON-PAREIL SEEDS | | | | | | |
| 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 | | | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| SUGARS (UNIDENTIFIED) | | | | | | |
| 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 | |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| TALC | 014807966 | | | | | |
| ORAL; TABLET, FILM COATED | | 27 | | 11/30/95 | 600 | 0.189MG - 204.0MG |
| ORAL; TABLET, REPEAT ACTION | | 2 | | 03/31/81 | UNK | 73.933MG |
| ORAL; TABLET, SUSTAINED ACTION | | 25 | | 11/14/94 | UNK | 0.1MG - 91.0MG |
| ORAL-21; TABLET | | 5 | | 12/14/92 | 510 | 0.2MG - 3.0MG |
| ORAL-28; TABLET | | 8 | | 12/14/92 | 510 | 0.19MG - 3.0MG |
| SUBLINGUAL; TABLET | | 2 | | 04/16/81 | 600 | 5.0MG |
| TOPICAL; LOTION | | 1 | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| TOPICAL; POWDER | | 1 | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| TALL OIL | 008002264 | | | | | |
| TOPICAL; SPONGE | | 1 | | | | |
| TALLOW GLYCERIDES | | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 08/16/74 | 600 | 2.78% |
| TARTARIC ACID | 000087694 | | | | | |
| INTRAVENOUS; SOLUTION, INJECTION | | 1 | | | | |
| ORAL; TABLET | | 2 | | 06/12/79 | 600 | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| SUBLINGUAL; TABLET | | 2 | | 07/07/80 | 600 | |
| TARTARIC ACID, DL- | 000133379 | | | | | |
| 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 | | | | | | |
| TOPICAL; EMULSION, CREAM | | 2 | | 08/16/74 | 600 | 0.025% |
| TOPICAL; OINTMENT | | 2 | | 10/01/84 | 600 | 0.025% |
| TERPENE RESIN | 009003741 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| TERPINEOL, ALPHA | 000098555 | | | | | |
| TOPICAL; LOTION | | 1 | | | | |
| TETRAKIS(1-ISOCYANO-2-METHOXY-2-METHYL-PROPANE)-COPPER(I) TE | | | | | | |
| INTRAVENOUS; INJECTION | | 1 | | | | |
| THIAZOXIMIC ACID | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 04/19/95 | 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% |

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| TITANIUM DIOXIDE | 001309633 | | | | | |
| TOPICAL; SUSPENSION, SHAMPOO | | 3 | | 01/10/91 | 600 | 5.0% |
| TOCOPHEROL | 001406662 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| TRAGACANTH | 009000651 | | | | | |
| ORAL; POWDER, FOR RECONSTITUTION | | 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 | 000102761 | | | | | |
| ENDOCERVICAL; GEL | | 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 | 018641571 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| TRICHLOROMONOFLUOROMETHANE | 000075694 | | | | | |
| INHALATION; AEROSOL, METERED | | 17 | | 12/28/95 | 600 | 24.47% - 34.2805% |
| NASAL; AEROSOL, METERED | | 3 | | 02/14/94 | UNK | |
| ORAL; AEROSOL SPRAY | | 1 | | | | |
| TRIDECETH 10 | | | | | | |
| TOPICAL; EMULSION, AEROSOL FOAM | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| TRIETHYL CITRATE | 000077930 | | | | | |
| ORAL; CAPSULE, ENTERIC COATED PELLETS | | 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 | | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| TRIHYDROXYSTEARIN | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TRILANETH-4 PHOSPHATE | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |
| TRILAURETH 4 PHOSPHATE | | | | | | |
| TOPICAL; OINTMENT | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

| INGREDIENT<br>ROUTE/DOSAGE FORM | CAS # | NDA COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| TRIMYRISTIN | | | | | | |
| ORAL; TABLET | | 1 | | | | |
| TRISTEARIN | 000555431 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| TRITHIAZOXIMIC ACID | | | | | | |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| TRITON X-200 SODIUM SALT OF ALKYLAURYL POLYETHER SULFONATE | | | | | | |
| TOPICAL; SHAMPOO | | 1 | | | | |
| TROLAMINE | 000102716 | | | | | |
| RECTAL; EMULSION, AEROSOL FOAM | | 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 | | 12/07/92 | UNK | 0.25% - 1.8% |
| TOPICAL; SPONGE | | 1 | | | | |
| VAGINAL; EMULSION, CREAM | | 2 | | 01/27/87 | 520 | 0.75% |
| TROLAMINE LAURYL SULFATE | | | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| TOPICAL; SHAMPOO | | 4 | | 09/18/84 | 600 | 35.0% - 77.8% |
| TROMETHAMINE | 000077861 | | | | | |
| INTRA-ARTERIAL; INJECTION | | 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 | 025301024 | | | | | |
| OPHTHALMIC; SOLUTION | | 5 | | 05/25/94 | 600 | 0.05% - 0.1% |
| OPHTHALMIC; SUSPENSION | | 4 | | 07/21/89 | UNK | 0.05% - 0.1% |
| UNION 76 AMSCO-RES 6038 | | | | | | |
| TRANSDERMAL; FILM, CONTROLLED RELEASE | | 1 | | | | |
| UNSPECIFIED INGREDIENT | | | | | | |
| 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 COUNT | LAST NDA | APPROVAL 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 | | 10/03/77 | 600 | 0.05MG - 0.16MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 2 | | 10/26/84 | 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 | | 12/28/87 | 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| VEGETABLE SHORTENING | | | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| VINYL ACETATE - CROTONIC ACID COPOLYMER | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| VINYL CHLORIDE | 000075014 | | | | | |
| ORAL; TABLET | | 1 | | | | |
| VISCARIN | 008047254 | | | | | |
| ORAL; SYRUP | | 1 | | | | |
| VITAMIN E | 000059029 | | | | | |
| 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 | | | | | | |
| IM - IV; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| IV(INFUSION); POWDER, FOR INJECTION SOLUTION | | 1 | | | | |
| WAX | | | | | | |
| ORAL; TABLET, FILM COATED | | 1 | | | | |
| WAX BLEND | | | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 1 | | | | |
| ORAL; TABLET | | 1 | | | | |
| WAX, DEHYDAG | 008023403 | | | | | |
| ORAL; TABLET, COATED | | 1 | | | | |
| TOPICAL; EMULSION, CREAM | | 1 | | | | |
| WAX, EMULSIFYING | 008014388 | | | | | |
| 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 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; CAPSULE, SUSTAINED ACTION | | 6 | | 05/10/93 | 180 | 1.4MG - 7.183MG |
| ORAL; TABLET | | 30 | | 10/06/95 | UNK | 0.01MG - 0.25MG |
| ORAL; TABLET, COATED | | 23 | | 09/10/87 | 600 | 0.018MG - 3.0MG |
| ORAL; TABLET, DELAYED ACTION, ENTERIC COATED | | 1 | | | | |
| ORAL; TABLET, ENTERIC COATED PARTICLES | | 1 | | | | |
| ORAL; TABLET, FILM COATED | | 3 | | 09/03/76 | 600 | 0.03MG - 0.2MG |
| ORAL; TABLET, REPEAT ACTION | | 2 | | 03/31/81 | UNK | 0.037MG |
| ORAL; TABLET, SUSTAINED ACTION | | 14 | | 01/04/95 | 600 | 0.06MG - 14.0MG |
| RECTAL; SUPPOSITORY | | 2 | | 09/02/77 | UNK | 187.5MG |
| 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 COUNT | LAST NDA | APPROVAL DATE | DIV | POTENCY RANGE |
|---|---|---|---|---|---|---|
| WAX, WHITE | 008006404 | | | | | |
| TOPICAL; OINTMENT | | 5 | | 04/30/87 | UNK | 5.0% - 6.0% |
| TOPICAL; OINTMENT, AUGMENTED | | 2 | | 08/31/95 | 600 | 6.0% |
| VAGINAL; EMULSION, CREAM | | 1 | | | | |
| WAX, YELLOW | 008012893 | | | | | |
| ORAL; CAPSULE | | 1 | | | | |
| ORAL; CAPSULE, SOFT GELATIN | | 1 | | | | |
| ORAL; TABLET | | 4 | | 12/08/87 | 600 | 0.06MG - 0.075MG |
| ORAL; TABLET, COATED | | 4 | | 05/06/74 | 600 | 0.15MG - 0.296MG |
| WECOBEE FS | | | | | | |
| VAGINAL; SUPPOSITORY | | 1 | | | | |
| WITEPSOL E-85 | | | | | | |
| VAGINAL; TAMPON | | 1 | | | | |
| WITEPSOL W-35 | | | | | | |
| RECTAL; SUPPOSITORY | | 1 | | | | |
| XANTHAN GUM | 011138662 | | | | | |
| 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 | | | | | | |
| ORAL; PASTILLE | | 1 | | | | |
| ORAL; SOLUTION | | 1 | | | | |
| ORAL; SOLUTION, ELIXIR | | 1 | | | | |
| ORAL; SUSPENSION | | 1 | | | | |
| ORAL; SYRUP | | 5 | | 03/22/85 | 600 | |
| ORAL; TABLET | | 1 | | | | |
| ZEIN | 009010666 | | | | | |
| ORAL; TABLET, REPEAT ACTION | | 2 | | 03/31/81 | UNK | 4.71MG |
| ORAL; TABLET, SUSTAINED ACTION | | 8 | | 11/14/94 | UNK | 4.5MG - 135.0MG |
| ZEOLEX | | | | | | |
| ORAL; TABLET, SUSTAINED ACTION | | 1 | | | | |
| ZINC ACETATE | 000557346 | | | | | |
| SUBCUTANEOUS; INJECTION | | 3 | | 06/25/91 | 510 | 0.015% |
| TOPICAL; LOTION | | 1 | | | | |
| TOPICAL; SOLUTION | | 1 | | | | |
| TOPICAL; SWAB | | 1 | | | | |

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

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

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

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) PHENLAMINO]ANTHRAQUINONE
16,23-DIHYDRODINAPTHO[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-6,15-DIHYDRO-5,9,14,18-ANTHRAZINETETRONE
16,17-DIMETHOXYDINAPTHO[1,2,3-CD:3',2',1'-lM]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
CUDBEAR
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)