DEPARTMENT OF HEALTH & HUMAN SERVICES JUN 22 1998 Public Health Service

Food and Drug Administration
Rockville MD 20857

Z152886

FOI SERVICES INC
11 FIRSTFIELD RD
GAITHERSBURG, MD 20878-1703

06/09/98

In reply refer to:
98003174

Your reference:
152886

Dear Requester:

This is in response to your request for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

INACTIVE INGREDIENT GUIDE 1997

Enclosed is (are) the requested record(s).

The following charges for this request to date may be included in a monthly invoice:

Reproduction	Search	Review	Postage	Other	Total
$	$3.50	$0.00	$0.00	$0.00	$

The above total may not reflect final charges for this request. Please do not send payment unless you receive an invoice.

All communications concerning this request should be identified with the reference number above and addressed as follows:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,
Mary Sejas

MARY L. SEJAS
LEAD INFORMATION TECHNICIAN

(301)827-6563

Enclosures:
if indicated

foi

FOI Services, Inc.
11 Firstfield Road
Gaithersburg MD 20878-1703 USA
Phone: 301-975-9400
Fax: 301-975-0702

FOOD & DRUG ADMINISTRATION
FREEDOM OF INFORMATION STAFF
5600 FISHERS LANE
ROCKVILLE, MD 20857

1/30/98

CONTROL NUMBER 152886

PURSUANT TO THE PROVISIONS OF THE FREEDOM OF INFORMATION ACT, PLEASE PROVIDE US WITH A PAPER COPY (PREFERABLY NOT MICROFICHE) OF THE FOLLOWING DOCUMENTS. IF THE COST OF PROVIDING THESE DOCUMENTS WILL EXCEED 100.00, PLEASE CALL US FIRST FOR AUTHORIZATION OF THE CHARGES, UNLESS INDICATED OTHERWISE BELOW.

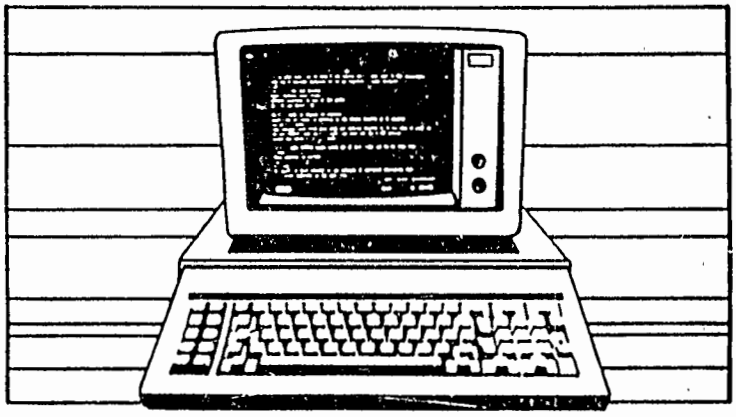
PLEASE REFER TO OUR CONTROL NUMBER IN YOUR REPLY.

COPY OF THE 1997 INACTIVE INGREDIENT GUIDE.

98-3174

HFI-30

INACTIVE INGREDIENT GUID



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 condi
approved drug products currently marketed for human use. The *Guide* is compiled by the Division of Drug Infor
Resources (DDIR). It provides CDER/CBER Reviewers with information on inactive ingredients in products which hav
approved by the Agency Once an inactive ingredient appears in a currently approved drug product for a particular r
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 adminis
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: "I
ingredient means any component other than the active ingredient. Active ingredient means any component that is in
to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of d
or to affect the structure or any function of the body of man or animals. The term (active ingredient) includes
components that may undergo chemical change in the manufacture of the drug product and be present in the finish
product in a modified form intended to furnish the specified activity or effect." As an exception of the CFR definition, i
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 ingredien
synonyms (which do not appear in the *Inactive Ingredient Guide*), it may assist you to contact your Drug Information
if you cannot find a particular inactive ingredient.

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

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

[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 carcinogenic, teratogenic, or embryotoxic, please notify DDIR immediately. DDIR will attempt to relay your concern to medical officer and pharmacologist reviewer responsible for oversight of other approved drug products which contai specified inactive ingredient.

CAS Number Many inactive ingredients have Chemical Abstracts Service (CAS) numbers associated with them. Thes be found in the column to the right of the inactive ingredient. CAS numbers may be helpful to CDER/CBER Reviewers 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 CT' reflects the total number of NDAs in which a particular inactive ingredient currently appears. The **'Last NDA'** spe which NDA was the most recent one to be approved by the Agency with this inactive ingredient. The **'APPROVAL DATE** 'DIV' specify the approval date and Review Division responsible for evaluating this most recent NDA. The **'POTENCY RA** specifies the minimum and maximum amounts of inactive ingredients for each route of administration and dosage form some cases, values in the **'POTENCY RANGE'** column have been collapsed into percentage of the total product in ord integrate data

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

Inactive Ingredient Structures Chemical structures of all inactive ingredients which have been submitted to the Agenc 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 specialized searches on the automated data base from which the *Inactive Ingredient Guide* is generated. For assistance in the *Guide*, to schedule a presentation on the *Guide*, or for a more detailed search, contact your DDIR Drug Information O on the following page or Mark Askine at 443-0500.

The information in the *Inactive Ingredient Guide* is not to be released verbally or in writing. Much of the information in this report is considered proprietary, and should, therefore, be treated as confidential.

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