



Z152886

Food and Drug Administration
Rockville MD 20857

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

IPR2015-01099
IPR2015-01097
IPR2015-01100
IPR2015-01105

Lupin EX1118
Page 1



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.

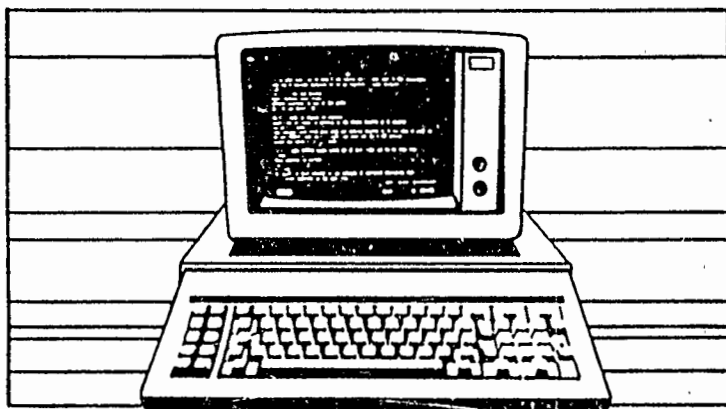
PLEASE REFER TO OUR CONTROL NUMBER IN YOUR REPLY.

COPY OF THE 1997 INACTIVE INGREDIENT GUIDE.

HFI-CU

98-3174
RECEIVED
FEB 3 - 1998
FDA FOI STAFF (202-335-3300)

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 conditions of use for 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 components that may undergo chemical change in the manufacture of the drug product and be present in the finished 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 Specialist if you cannot find a particular inactive ingredient.

Proprietary Inactive Ingredients DDIR does not always include the components of proprietary inactive ingredients (OPACODES). In such situations where components of proprietary inactive ingredients are included, you may have to refer to 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 carcinogenic, teratogenic, or embryotoxic, please notify DDIR immediately. DDIR will attempt to relay your concern to the 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 numbers can be found in the column to the right of the inactive ingredient. CAS numbers may be helpful to CDER/CBER Reviewers and sponsors in 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 'TOTAL NDAs' 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 and 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 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.

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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.