

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

AUG 1 1 1999

Freedom of Information Staff HFD-205

5600 Fishers Lane 12 B 05 Rockville, Maryland 20857

Center for Drug Evaluation and Research Office of Training and Communication

August 9, 1999

In Response Refer to File: F99-10503



FOI Services, Inc. 11 Firstfield Road Gaitherburg, MD 20878-1703

Dear Requester:

This is in response to your request of May 4, 1999, in which you requested a copy of the approval package for NDA 20766. Your request was received in the Center for Drug Evaluation and Research on May 7, 1999.

The documents you have requested are enclosed. "In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the record(s) indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address:

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

Should the Agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal." SMG 2460.7(3)

This concludes the response for the Center for Drug Evaluation and Research.

(Search \$29.00, Review \$261.00, Reproduction \$ Computer time \$0.00) will be included in a monthly invoice. DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.



If there are any problems with this response, please notify us <u>in writing</u> of your specific problem(s). Please reference the above file number.

Sincerely,

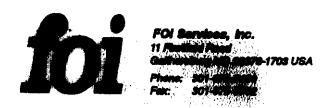
J. Santford Williams, R.P.h

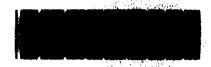
J. Santford Williams, R.Ph.
Freedom of Information Officer
Office of Training and Communications
Freedom of Information Staff, HFD-205
Direct Line (301)827-4583

Enclosure:

904 pages, approval package for NDA 20766







FOOD & DRUG ADMINISTRATION FREEDOM OF INFORMATION STAFF 5600 FISHERS LANE ROCKVILLE, MD 20857 5/ 4/99

CONTROL NUMBER 160880

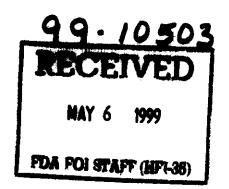
A510.

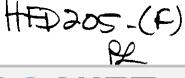
PURSUANT TO THE PROVISIONS OF THE FREEDOM OF INFORMATION ACT, PLEASE PROVIDE US WITH A PAPER COPY (PREFERABLY NOT MICROFICHE) OF THE FOLLOWING DOCUMENTS. IF THE COST OF PROVIDING THESE DOCUMENTS WILL EXCEED 100.00, PLEASE CALL US FIRST FOR AUTHORIZATION OF THE CHARGES, UNLESS INDICATED OTHERWISE BELOW.

PLEASE REFER TO THE METHOL NUMBER IN YOUR REPLY.

ATTN: CENTER FOR DRUGS

COPY OF THE DISCLOSABLE APPROVAL DOCUMENTATION FOR XENICAL (ORLISTAT) CAPSULES SPONSORED BY HOFFMANN-LAROCHE, APPROVED 4/26/99.







CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020766

Trade Name: XENICAL CAPSULES 120 MG

Generic Name: ORLISTAT

Sponsor: HOFFMAN-LA ROCHE

Approval Date: 04/23/99

INDICATION(s): FOR OBESITY MANAGEMENT INCLUDING WEIGHT LOSS AND WEIGHT MAINTENANCE WHEN USED IN CONJUNCTION WITH A REDUCED CALORIE DIET.



CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 020766

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Printed Labeling	X			
Medical Review(s)	X			- · · · · · · · · · · · · · · · · · · ·
Chemistry Review(s)	X			· · · · · · · · · · · · · · · · · · ·
EA/FONSI	X			<u>.</u>
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)		···		X
Clinical Pharmacology	X			
Biopharmaceutics Review(s)				
Bioequivalence Review(s)				X
Administrative/				
Correspondence Document(s)	\mathbf{X}			

DOCKET

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.

