



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Center for Drug Evaluation and Research
Office of Training and Communication
Freedom of Information Staff HFD-205
5600 Fishers Lane 12 B 05
Rockville, Maryland 20857

AUG 11 1999

August 9, 1999

In Response Refer to File : F99-10503



FOI Services, Inc.
11 Firstfield Road
Gaithersburg, 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.

Charges of \$ (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.**

EXHIBIT

Ex. 1013

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

Sincerely,

J. Santford Williams, R.Ph.

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



FOI Services, Inc.
 11 Franklin Place
 Gaithersburg, MD 20878-1703 USA
 Phone: 301-928-0000
 Fax: 301-928-0002



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 CONTROL 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.

99-10503
RECEIVED
 MAY 6 1999
 FDA FOI STAFF (MP-38)

HF 205-(F)
 RL

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			
Tentative Approval Letter				X
Approvable Letter				X
Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
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)	X			

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