DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 1 1 1999

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.

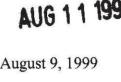
The documents you have requested are enclosed. "In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the record(s) indicated that the deleted information is not required to be publicly disclosed. If, however,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

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.**



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





DOCKE

Ex. 1013

EXHIBI

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



5/ 4/99

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

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 GER MUMBER 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 **May 6** PDA FOI STAFF (HFI-35)



RM

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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.

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 020766

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DOCKET

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	··· · · · · · · · · · · · · · · · · ·		
Pharmacology Review(s)	X			
Statistical Review(s)	Х		· · · · · · · · · · · · · · · · · · ·	
Microbiology Review(s)				X
Clinical Pharmacology	X			
Biopharmaceutics Review(s)				
Bioequivalence Review(s)				X
Administrative/				
Correspondence Document(s)	X			

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