



**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

**2160880**

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.**

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 Rutland Road  
Gatherings, NY 10979-1703 USA  
Phone: 301-625-0000  
Fax: 301-625-0002

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

5/ 4/99

CONTROL NUMBER 160880

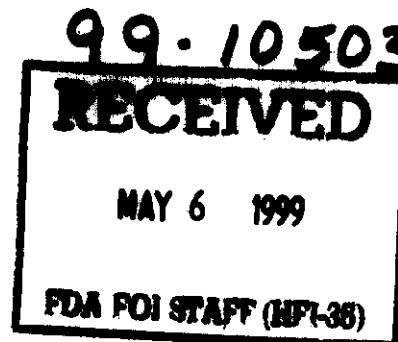
A510.

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 OUR 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.



HF205-(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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