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## Glucophage 500 and 850 mg Tablets (Lipha Pharmaceuticals) 12/29/1994 Approval: Approval Letter, Pediatric Studies, Labeling

**This document was provided by: FOI Services, Inc**

11 Firstfield Road  
Gaithersburg MD 20878-1704 USA  
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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

JAN 08 1998

December 30, 1997

In Response Refer to File : F97-41306

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

2151966

Dear Requestor:

This is in response to your request of December 11, 1997, your control number 151966, in which you requested documents for the drug METFORMIN. Your request was received in the Center for Drug Evaluation and Research on December 17, 1997.

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 \$7.00, Review \$0.00, 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,



Sandra James  
Freedom of Information Technician  
Office of Training and Communication  
Freedom of Information Staff HFD-205  
Direct Line (301) 827-3459

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THANK-YOU FOR YOUR REQUEST AND UNDERSTANDING.

**FREEDOM OF INFORMATION STAFF**

**foi**

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

12/11/97

CONTROL NUMBER 151966

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.

COPY OF ALL CORRESPONDENCE DONE IN THE CENTER FOR DRUG EVALUATION AND RESEARCH FOR THE APPROVAL OF METFORMIN HCL (TABLETS).

97.41306  
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DEC 16 1997

FDA FOI STAFF (HH-35)

HFID205

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