

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20405

Trade Name: LANOXIN

Generic Name: DIGOXIN

**Sponsor: GLAXO WELLCOME RESEARCH
AND DEVELOPMENT**

Approval Date: SEPTEMBER 30, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20405

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final 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 Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
Administrative Document(s)	X			
Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20405

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-405

SEP 30 1997

Glaxo Wellcome Research and Development
Attention: Ms. Elizabeth A. Nies
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Nies:

Please refer to your September 30, 1993 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lanoxin (digoxin) 62.5, 125, 187.5, 250, 375 and 500 mcg Tablets.

We acknowledge receipt of your correspondence and amendments dated June 2 and 6, July 3 and 29, August 4 and September 15, 1997.

This new drug application provides for the use of Lanoxin Tablets for the treatment of heart failure in patients receiving angiotensin-converting enzyme inhibitors and diuretics or diuretics alone and for the control of ventricular response rate in patients with chronic atrial fibrillation.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-405. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We note that you have decided not to market the 62.5, 187.5, 375 and 500 mcg tablet strengths at this time. Only the 125 mcg and 250 mcg tablet strengths are approved to be manufactured at your Zebulon, North Carolina facility.

The dissolution specifications for this product are:

Q= at 60 minutes and quantity of digoxin tablet dissolved in 60 minutes from each tablet must not be less than of the labeled strength at level 1 (number of tablets tested = 6).

Average of digoxin dissolved in 60 minutes for a total of 12 tablets is not less than of the labeled strengths and quantity of digoxin dissolved in 60 minutes from each tablet is not less than of the labeled strength at level 2 (Number of tablets tested = 12).

The 15 minute test should be dropped.

Please submit one market package of the drug when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,



Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20405

APPROVABLE LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

DF
Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-405

JUN 2 1997

Glaxo Wellcome Inc.
Attention: Ms. Elizabeth A. Nies
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Nies:

Please refer to your September 30, 1993 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lanoxin (digoxin) 62.5, 125, 187.5, 250, 375 and 500 mcg Tablets.

We acknowledge receipt of your correspondence and amendments dated March 4 and 26, July 3 and 17, August 5, 15, 16 and 19, September 24 and 26, November 18, 1996; March 7 and 20, April 7, 11 and 30, and May 5, 1997.

We have completed the review of this application as submitted with draft labeling and it is approvable. Before the application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed marked-up draft. If additional information relating to the safety or effectiveness of this drug becomes available, revision of the FPL may be required.

Please submit sixteen copies of the printed labels and other labeling, ten of which are individually mounted on heavy weight paper or similar material.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

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Should you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
Telephone: (301) 594-5332

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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cc:

Original NDA
HFD-2/MLumpkin

HFD-101

~~HFD-92~~

HFD-110

HFD-40 (with draft labeling)

DISTRICT OFFICE

HFD-110/GBuehler/5/20/97

sb/5/21/97;5/27/97

R/D: DCunningham/5/23/97

RWolters/5/22/97

EFadiran/5/23/97

AParekh/5/23/97

WNuri/5/23/97

NMorgenstern/5/23/97

APPROVABLE