CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020241/S003 AND 020764/S001

Trade Name: LAMICTAL TABLETS and CHEWABLE DISPERSABLE TABLETS

Generic Name: LAMOTRIGINE

Sponsor: GLAXO WELLCOME, INC

Approval Date: 12/14/98

INDICATION(s): TREATMENT IN ADULTS WITH PARTIAL SEIZURES

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APPLICATION: 020241/S003 AND 020764/S001

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter			X	
Approvable Letter			X	
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/ Correspondence Document(s)	X			

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Application Number: 020241/S003 AND 020764/S001

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-241/S-003
NDA 20-764/S-001

DEC 14 1998

Glaxo Wellcome Inc.
Attention: Elizabeth A. McConnell, Pharm.D.
Project Director, Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. McConnell:

Please refer to your supplemental new drug applications dated February 24, 1997 (NDA 20-241/S-003), and September 4, 1998 (NDA 20-764/S-001), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamictal (lamotrigine) Tablets and Lamictal (lamotrigine) Chewable Dispersible Tablets.

We acknowledge receipt of your additional amendment to these supplemental applications dated October 20, 1998.

These supplemental new drug applications provide for the use of Lamictal (lamotrigine) Tablets and Lamictal (lamotrigine) Chewable Dispersible Tablets as conversion to monotherapy in adults with partial seizures who are receiving treatment with a single enzyme-inducing anti-epileptic drug (EIAED).

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-241/S-003, 20-764/S-001." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, contact Jacqueline H. Ware, Pharm.D., Regulatory Management Officer, at (301) 594-2850.

Sincerely yours,

/S/ 12/17/98

APPEARS THIS WAY
ON ORIGINAL

Paul Leber, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

APPEARS THIS WAY
ON ORIGINAL