

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 20763

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 20-763

Food and Drug Administration
Rockville MD 20857

Glaxo Wellcome Inc.
Attention: James E. Murray
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709

FEB 10 1998

Dear Mr. Murray:

Please refer to your new drug application dated December 4, 1996, received December 4, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amerge (naratriptan) 1 mg and 2.5 mg tablets.

We acknowledge receipt of the following submissions:

December 16, 1996	April 15, 1997	July 3, 1997	September 11, 1997
January 14, 1997	May 1, 1997 (2)	July 9, 1997 (2)	October 7, 1997
January 23, 1997	May 8, 1997	July 25, 1997	October 17, 1997
February 7, 1997	May 15, 1997	July 29, 1997	November 21, 1997
February 12, 1997	May 27, 1997 (2)	August 1, 1997	November 26, 1997
February 19, 1997	June 3, 1997	August 5, 1997	December 1, 1997 (2)
February 26, 1997	June 6, 1997	August 6, 1997	December 15, 1997
February 27, 1997	June 10, 1997	August 7, 1997	December 17, 1997
March 10, 1997	June 24, 1997	August 20, 1997	January 15, 1998
March 17, 1997	June 26, 1997	August 29, 1997	January 16, 1998
April 2, 1997	June 30, 1997	September 2, 1997	
April 10, 1997	July 1, 1997	September 4, 1997	

The original User Fee goal date for this application was December 4, 1997. Your submission of November 21, 1997 extended the User Fee goal date to March 4, 1998.

This new drug application provides for the acute treatment of migraine headache.

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 labeling text. Accordingly, the application is approved effective on the date of this letter.

Please adopt the following dissolution method and specifications:

The approved expiration date is 24 months at controlled room temperature (per USP).

The final printed labeling (FPL) must be identical to the enclosed labeling text. 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 20 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 20-763. 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.

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 the Division of Neuropharmacological Drug Products 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

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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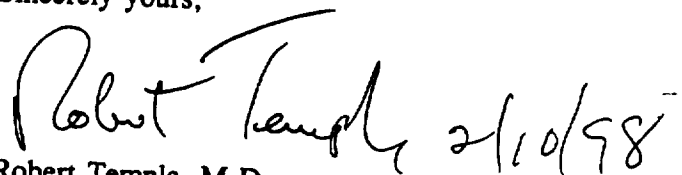
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Please submit one market package of the drug product when it is available.

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 Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely yours,

A handwritten signature in cursive script that reads "Robert Temple" followed by the date "2/10/98".

Robert Temple, M.D.

Director

Office of Drug Evaluation I

Center for Drug Evaluation and Research

ENCLOSURE