CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 20763

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

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:

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<tr>
<th>Date</th>
<th>Submission Date</th>
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<tr>
<td>January 14, 1997</td>
<td>May 1, 1997 (2)</td>
<td>July 9, 1997 (2)</td>
<td>October 7, 1997</td>
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<td>February 12, 1997</td>
<td>May 27, 1997 (2)</td>
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<td>April 10, 1997</td>
<td>July 1, 1997</td>
<td>September 4, 1997</td>
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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.
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,

[Signature]

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE