CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20768

Trade Name: ZOMIG

Generic Name: ZOLMITRIPTAN

Sponsor: ZENECA PHARMACEUTICALS

Approval Date: NOVEMBER 25, 1997

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APPLICATION: NDA 20768

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	Included	Pending Completion	Not Prepared	Not Required
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EA/FONSI	X			
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Statistical Review(s)	X			
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APPLICATION NUMBER: NDA 20768

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-768

Zeneca Pharmaceuticals
Attention: Kevin McKenna, PhD
1800 Concord Pike
PO Box 15457
Wilmington, DE 19850-5437

NOV 25 1997

Dear Dr. McKenna:

Please refer to your new drug application dated November 26, 1996, received November 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zomig (zolmitriptan) 2.5mg and 5.0 mg tablets.

We acknowledge receipt of your submissions dated:

December 10, 1996	February 3, 1997	June 5, 1997 (2)	October 1, 1997
December 13, 1996	February 28, 1997	June 26, 1997	October 21, 1997
January 8, 1997	March 7, 1997	July 8, 1997	October 29, 1997
January 15, 1997	March 24, 1997	July 14, 1997	November 6, 1997
January 30, 1997	May 19, 1997	August 13, 1997	November 21, 1997 (2)
January 31, 1997	May 21, 1997	August 25, 1997 (2)	

The User Fee goal date for this application is November 26, 1997.

This new drug application provides for the use of Zomig Tablets in the treatment of migraine headaches.

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 marked-up 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 marked-up draft labeling. Marketing the product before making the agreed upon revisions in the product's 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 20-768. 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 remind you of your Phase 4 commitments specified in your submission dated November 6, 1997. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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,

Robert Temple

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