DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-231

AstraZeneca Pharmaceuticals LP
Attention: Ms. Judy Firor
1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437

Dear Ms. Firor:

Please refer to your new drug application (NDA) dated April 14, 2000, received April 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zomig-ZMT (zolmitriptan) orally disintegrating tablets.

We acknowledge receipt of your submissions dated the following:

April 14, 2000	October 9, 2000	January 16, 2001
May 26, 2000	November 29, 2000	January 19, 2001
June 28, 2000	December 6, 2000	February 2, 2001
August 14, 2000	January 9, 2001	February 13, 2001
September 18, 2000	January 11, 2001	

This new drug application provides for the use of Zomig-ZMT (zolmitriptan) orally disintegrating tablets for acute treatment of migraine.

We have completed the review of this application, as amended, 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 agreed upon enclosed labeling text. Accordingly, the application is 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), with the exception of the modification requested to figure 3 in the "Note to Sponsor" on page 9. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 "FPL for approved NDA 21-231." Approval of this submission by FDA is not required before the labeling is used.

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.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you did not address the pediatric rule in your submission. However, the Agency has issued a pediatric written request letter dated March 26, 1999, to the Zomig IND 45,147 and NDA 20-768 informing you of the types of studies required to develop zolmitriptan in adolescent migraine (age range 12 to 17 years old). We request that you submit your pediatric development plan for assessing pediatric safety and effectiveness. If this pediatric development plan was previously submitted to IND 45,147 and/or NDA 20-768, you may simply submit a letter cross referencing that submission. We are deferring submission of your pediatric studies until July 1, 2002.

In addition, please submit three copies of the introductory promotional materials 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 materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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, call Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-5529.

Sincerely,

{See appended electronic signature page}

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

Enclosure