DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-768/SLR-010
NDA 21-231/SLR-003

AstraZeneca Pharmaceuticals LP
US Regulatory Affairs
Attention: Judy W. Firor
1800 Concord Pike
PO Box 15437
Wilmington, DE 19803-5437

Dear Ms. Firor:

Please refer to your supplemental new drug applications dated July 1, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zomig (zolmitriptan) tablets and Zomig-ZMT (zolmitriptan) orally disintegrating tablets.

These supplemental applications provide for adding the terms *anaphylaxis* or *anaphylactoid reaction* in the *Adverse Reactions, Post-Marketing Experience* section, under subheading *General.* These supplements were submitted in response to FDA letter dated January 24, 2002.

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 submitted final printed labeling (package insert, patient package insert submitted July 1, 2002 Label Code SIC 64192-02), which incorporates all of the revisions listed. Accordingly, these supplemental applications are approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental applications are permitted by section 314.70(c) of the regulations to be instituted prior to approval of these supplements. It is understood that the changes, described in the above NDA supplements, have been made.

If a letter communicating important information about these drug products (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 these NDAs 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, call Ms. Lana Chen, R.Ph., Regulatory Project Manager, 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

10/9/02 04:55:29 PM