DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-768/SLR-011
NDA 21-231/SLR-004

AstraZeneca Pharmaceuticals LP
Attention: Judy W. Firor
US Regulatory Affairs
1800 Concord Pike
PO Box 8355
Wilmington, DE 19850-8355

Dear Ms. Firor:

Please refer to your supplemental new drug applications dated November 5, 2002, received November 6, 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 "Changes Being Effected" supplemental applications provide for the addition of post-marketing changes to the Warnings section regarding cardiac events, change in title of the Use in Elderly subsection, addition of post-marketing changes to the Precautions section regarding adverse events, updating the trademark for Zomig-ZMT, and changes to the Patient Package Insert.

We have completed the review of these supplemental applications, 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 November 5, 2002), 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

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