DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-768/S-006

Judy W. Firor
US Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
PO Box 8355
Wilmington, DE 19803-8355

Dear Ms. Firor:

Please refer to your supplemental new drug application(s) dated January 20, 2000, received January 26, 2000, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zomig (zolmitriptan) tablets.

Reference is also made to your May 9, 2001 amendment received May 10, 2001 and to our March 19, 2001 approvable letter. Your submission of May 9, 2001 constituted a complete response to our March 19, 2001 approvable letter.

This supplemental new drug application provides for revised carton and container labeling.

We have completed the review of this/these application(s), as amended, and have concluded that adequate information has been presented to demonstrate that the drug products is safe and effective for use as recommended in the agreed upon labeling text. Accordingly the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted May 9, 2001), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-768/S-006." Approval of this submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (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 this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 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, Regulatory Project Manager, at (301) 594-5529.

Sincerely,

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

1/29/02 04:57:03 PM