DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-450

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

Dear Ms. Firor:

Please refer to your new drug application (NDA) dated March 27, 2003, received March 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zomig (zolmitriptan) Nasal Spray.

We acknowledge receipt of your submissions dated April 17, April 25, August 29, and September 30, 2003 .

The March 27, 2003 submission constituted a complete response to our December 19, 2002 action letter.

This new drug application provides for the use of Zomig (zolmitriptan) Nasal Spray for the acute treatment of migraine.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). 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 an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-450**." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your phase 4 commitment, as discussed in a teleconference held on August 28, 2003 and in your letter dated August 29, 2003, to provide the following information to support approval of (b)(4)---------- --- ---------- spray devices.
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1. The results of an open-label, randomized, two-period crossover bioequivalence study comparing two single 5 mg doses of zolmitriptan (ZOMIG®) administered to healthy volunteers in the two nasal spray devices used in the clinical development program. The study will assess the bioequivalence of the two devices after single dose administration of zolmitriptan to healthy volunteers with particular regard to AUC, C_{max}, and t_{max}. You commit to submit the results of this trial within 6 months of the date of this letter.

2. Additional data in support of the(b)(4)----------(details to be subsequently agreed to with the FDA) and to submit the----------he submission of the 5 mg bioequivalence study.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Lana Chen, 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

Enclosure

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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