DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-768/S-012

Matthew E. Arnold
Regulatory Project Manager
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
PO Box 8355
Wilmington, DE 19803-8355

Dear Mr. Arnold:

Please refer to your supplemental new drug application dated May 18, 2004, received May 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zomig (zolmitriptan) tablets.

We acknowledge receipt of your submission dated October 14, 2004.

Your submission of May 18, 2004 constituted a complete response to our March 30, 2004 action letter.

This supplemental new drug application proposes the use of Zomig (zolmitriptan) tablets for the acute treatment of migraine in adolescents. Your May 18, 2004 submission provides for inclusion of the description of the adolescent clinical trial in labeling.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below.

In the Pediatric Use subsection, please delete the "to" in the first sentence of the second paragraph.

Pediatric Use

Safety and effectiveness of ZOMIG Tablets in pediatric patients have not been established. Therefore, ZOMIG is not recommended for use in patients under 18 years of age.

One randomized, placebo-controlled clinical trial evaluating zolmitriptan tablets (2.5, 5 and ~~to~~ 10 mg) in pediatric patients aged 12-17 years evaluated a total of 696 adolescent migraineurs. This study did not establish the efficacy of zolmitriptan compared to placebo in the treatment of migraine in adolescents. Adverse events observed were similar in nature and frequency to those reported in clinical trials in adults.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to enclosed labeling (text for the package insert, text for the patient package insert. These revisions are terms of the approval of this application.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-768/S-012. Approval of this submission by FDA is not required before the labeling is used.

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 directly to:

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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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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