CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-001

CORRESPONDENCE

NDA 21-001

Pharmacia and Upjohn Co.
Attn: Marcia Rogers
7000 Portage Road
Kalamazoo, MI 49001

OCT 16 2000

Dear Ms. Rogers:

Please refer to your new drug application (NDA) dated December 17, 1999, received December 20, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Axert (almotriptan) tablets.

On September 6, 2000, we received your September 5, 2000 major amendment to this application. The receipt date is within 3 months of the primary user fee goal date. Therefore, we are extending the goal date by three months to provide time for a full review of the submission. The extended primary user fee goal date is January 20, 2001. The secondary user fee goal remains December 20, 2000.

If you have questions, call Lana Chen, Regulatory Project Manager, at (301) 594-5529.

Sincerely yours,

/S/ [illegible]

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-001

Pharmacia and Upjohn Co.
Attn: Ms. Marcia Rogers
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Rogers:

We acknowledge receipt of your January 23, 2001 resubmission, received January 24, 2001, and of your March 6, 2001 resubmission, received March 7, 2001 to your new drug application (NDA) for Axert (almotriptan) tablets.

Reference is made to our February 6 and February 14, 2001 teleconferences during which detailed clarification of the Chemistry information requested was discussed.

Your January 23, 2001 resubmission contains Clinical, Clinical Pharmacology, and Chemistry information submitted in response to our December 20, 2000 action letter. Your March 6, 2001 resubmission contains additional Chemistry information submitted in response to our December 20, 2000 action letter and our February 6 and February 14, 2001 teleconferences.

We consider these submissions a complete class 1 response to our action letter. Therefore, the primary user fee goal date is May 6, 2001.

If you have any questions, call Lana Chen, R. Ph., Regulatory Management Officer, at (301) 594-5529.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D. /S/ 3/20/01
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199
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Telephone: (616) 833-4000

Pharmacia & Upjohn

March 28, 2001

Division of Neuropharmacological Drug Products, HFD-120
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Woodmont II Building 4th Floor
1451 Rockville Pike
Rockville, MD 20852

Re: NDA 21-001
AXERT™ Tablets
(almotriptan malate tablets)

GENERAL CORRESPONDENCE
PROPOSED PEDIATRIC STUDY REQUEST AND PEDIATRIC DRUG DEVELOPMENT PLAN

Dear Sir/Madam:

Pharmacia & Upjohn is submitting this proposed pediatric study request and pediatric development plan to support pediatric exclusivity pursuant to section 505A of the Federal Food, Drug and Cosmetic Act.

The Food and Drug Administration (FDA) informed Pharmacia & Upjohn (P&U) on December 20, 2000 that NDA 21-001 for AXERT™ Tablets (almotriptan malate tablets) was approvable. As part of this letter, FDA asked P&U to commit to conducting, subsequent to approval, pediatric studies in order to evaluate the usefulness of almotriptan in adolescents (ages 12-17). This document outlines P&U's proposal for the pediatric study request and the resultant pediatric drug development plan. P&U is planning to conduct two pediatric studies to qualify for additional marketing exclusivity for almotriptan.

The overall goal of the development plan is to explore the efficacy and safety of almotriptan in the treatment of adolescent migraine. In addition, we wish to obtain other information, e.g., pharmacokinetic, pertinent to using the drug in the adolescent population.

Types of Studies

The designs of the proposed studies are described in the following pages of this submission, as noted below:

1) Adolescent Efficacy and Safety Study
An acute single headache efficacy and safety study is planned. The study title is as follows: " A Randomized, Double-Blind, Placebo-Controlled Study of Oral Almotriptan in the Treatment of Acute Migraine in Adolescents" *(pages 1– 6)*.

2) Adolescent Pharmacokinetic Study
The pharmacokinetics of almotriptan in adolescents will be compared to the pharmacokinetics in adults in an open label, parallel single dose study. The study will be entitled, " Almotriptan: Comparison of the Pharmacokinetics of Almotriptan in Healthy Adolescents and Adults" *(pages 7 – 9)*.

Labeling that May Result from the Studies

The adolescent migraine efficacy and safety, and pharmacokinetic studies described in this request could result in the addition to labeling pertinent to the planned studies.

Format of Reports to be Submitted

Full study reports, not previously submitted to the agency, with full analysis, assessments, and interpretation will be submitted to the Agency.

Timeframe for Submitting Reports of the Studies

Pharmacia & Upjohn will submit the appropriate study reports within 24 months of the latest date of the following:

1) Date of receipt of approval of almotriptan for use as an antimigraine agent in the adult population;

2) Date of receipt of a "Written Agreement for Pediatric Studies" from the Agency.

If you have any questions regarding this submission, please contact me at (616) 833-6579. Please send correspondence addressed to Unit 0635-298-113.

Sincerely,

PHARMACIA & UPJOHN COMPANY

Marcia J. Rogers
Regulatory Affairs Manager

MJR:lmf

Attachment

cc: Lana Chen, R Ph., Regulatory Management Officer