CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20753

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

A. Staton

Food and Drug Administration
Rockville MD 20857

NDA 20-753

Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

OCT 21 1999

Attention: Cecilia S. Blomqvist
Regulatory Manager

Dear Ms. Blomqvist:

Please refer to your new drug application (NDA) dated December 18, 1998, received December 21, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aromasin (exemestane) Tablets, 25 mg.

We acknowledge receipt of your submissions dated November 30, 1998; December 11 and 18, 1998; February 16, 23 and 25, 1999; March 3 and 16, 1999; April 22, 27 and 29, 1999; May 3 and 24, 1999; June 4 and 14, 1999; July 9, 12 and 30, 1999; August 11, 30 and 31, 1999; September 7, 10, 13, 14, 15 and 20, 1999; October 6, 7 and 11, 1999.

This new drug application provides for the use of Aromasin® (exemestane) Tablets, 25 mg for the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the 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 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-753." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Oncology Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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, contact Ann Staten, Regulatory Health Project Manager, at (301) 594-5770.

Sincerely,

/S/ 10/26/99

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure