CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
17-970/S-046

Approval Letter

NDA 17-970/S-046

AstraZeneca Pharmaceuticals
Attention: Anthony F. Rogers
Vice President, Regulatory Affairs
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

JUN 29 2000

Dear Mr. Rogers:

Please refer to your supplemental new drug application dated December 28, 1999, received December 29, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NOLVADEX (tamoxifen citrate).

We acknowledge receipt of your submissions dated January 14 and 20; February 28; March 20; April 3, 14 and 27; May 18 and June 1, 13 (2), 19, 20, 22 and 26, 2000.

This supplemental new drug application provides for the use of NOLVADEX (tamoxifen citrate) in women with DCIS, following breast surgery and radiation, Nolvadex is indicated to reduce the risk of invasive breast cancer.

We have completed the review of this supplemental 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 supplemental 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, text for the patient package insert).

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. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternately, 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 17-970/S-046." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your facsimile dated June 29, 2000. These commitments, along with any completion dates agreed upon, are listed below.

1. A commitment to address, in a labeling supplement, issues conveyed to you on June 22, 2000, regarding the Geriatric Use section of the labeling. The labeling supplement must be submitted to the Agency 3 months from the date of the approval of this supplement.

2. A commitment to address, in a labeling supplement, issues conveyed to you in FDA facsimiles dated June 28, 2000, regarding pharmacology/toxicology and biopharmaceutical sections of the labeling. This labeling supplement must be submitted to the Agency 3 months from the date of the approval of this supplement.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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 submit 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, Maryland 20857

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 Amy Baird, Consumer Safety Officer, at (301) 594-5771.

Sincerely,

6/29/00

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

cc:
Archival NDA 17-970/S-046
HFD-150/Div. Files
HFD-150/Baird
HFD-150/Honig/GrantWilliams/Sridhara/Chen/YHsieh/Wood/Brower/Booth/Rahman
HFD-150/Pease (with labeling)
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-101/ADRA (with labeling)
HFD-102/Post-Marketing PM
HFD-104/Peds/V.Kao (with labeling)
HFD-104/Peds/T.Crescenzi (with labeling)
HFD-42/DDMAC (with labeling)
HFI-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-095/DDMS-IMT (with labeling)
HFD-810/DNDC Division Director
DISTRICT OFFICE
R/D by: Baird-6-29-00
R/D init by: GrantWilliams-6-29-00/Rahman-6-29-00/Pease-6-29-00/Sridhara-6-29-00/
Yhsieh-6-29-00/Wood-6-29-00/Brower-6-29-00/Schmidt-6-29-00/
AR for Booth-6-29-00
F/T by: Baird-6-29-00

APPROVAL (AP) (with Phase 4 Commitments)