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APPLICATION NUMBER:

20-541/S-006

APPROVAL LETTER

Div File

NDA 20-541/S-006

SEP 1 2000

AstraZeneca Pharmaceuticals
Attention: Sandra Bihary, MSN
Executive Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Bihary:

Please refer to your supplemental new drug application dated November 1, 1999, received November 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ARIMIDEX® (anastrozole) Tablets.

We acknowledge receipt of your submissions dated November 24, 1999; February 1, 10, 15 and 18; May 31; June 20; July 18 and August 21 and 29, 2000.

This supplemental new drug application provides for the use of ARIMIDEX® (anastrozole) Tablets for the first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic 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). 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 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. Alternatively, 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 20-541/S-006." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your facsimile dated August 31, 2000. This commitment, along with any completion dates agreed upon, is listed below.

To submit annual safety and survival updates for studies 0027 and 0030 until 75% of the patients are deceased.

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

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this action on this application.

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 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, Project Manager, at (301) 594-5771.

Sincerely,

RSI

9/1/00

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 20-541/S-006
HFD-150/Div. Files
HFD-150/Baird
HFD-150/Odujinrin/Johnson/G. Chen/Yang/Brower/Duan/Rahman/Kim/Wood/Pease
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)
HF1-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-095/DDMS-IMT
HFD-093/DDMS-IST (with labeling)
HFD-810/DNDC Division Director
DISTRICT OFFICE
R/D by: Baird-08-31-00
R/D init by: Pease-8-31-00/Kim-9-1-00/Wood-9-1-00/Duan-8-31-00/Rahman-8-31-00/
Chen-9-1-00/Brower-8-31-00/Johnson-9-1-00
F/T by: Baird-9-1-00

APPROVAL (AP) (with Phase 4 Commitments)

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FINAL PRINTED LABELING