CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-541/S-010

Correspondence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-541/S-010

AstraZeneca Pharmaceuticals LP
Attention: Mark Scott, Ph.D.
Executive Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Dr. Scott:

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

We also refer to your December 21, 2001, request for fast track designation and for step-wise submission of sections of a supplemental new drug application under section 506 of the Act.

We have reviewed your request and have concluded that it meets the criteria for fast track designation. Therefore, we are designating ARIMIDEX (anastrozole) Tablets for adjuvant treatment of early breast cancer in postmenopausal women, as a fast track product.

We are granting fast track designation for the following reasons:

1. Postmenopausal women with early breast cancer are considered to have a serious disease that when left untreated may result in disease recurrence and death.

2. The sponsor submitted a summary from the ATAC trial data to support the fast track request. Data from 9366 postmenopausal women with early breast cancer may indicate that treatment with Arimidex is superior in the primary endpoint to Nolvadex (tamoxifen citrate), the current standard of adjuvant hormonal therapy.

We have also reviewed your request for step-wise submission of sections of a supplemental new drug application for the adjuvant treatment of postmenopausal breast cancer and have concluded that the proposed plan, described in your request, for its step-wise submission is acceptable.

If you pursue a clinical development program that does not support use of ARIMIDEX (anastrozole) Tablets for adjuvant indication (fix wording once request is received), we will not review the application or accept step-wise submission of sections of a supplemental new drug application under the fast track program.

If you have any questions, call Amy Baird, Consumer Safety Officer, at (301) 594-5771.

Sincerely,

{See appended electronic signature page}

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

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/s/

Richard Pazdur
12/21/01 03:56:10 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-541/S-010

PRIOR APPROVAL SUPPLEMENT

AstraZeneca Pharmaceuticals LP
Attention: Mark Scott, Ph.D.
Executive Director, Regulatory Affairs
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Dr. Scott:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: ARIMIDEX® (anastrozole) Tablets

NDA Number: 20-541

Supplement Number: S-010

Review Priority Classification: Priority (P)

Date of Supplement: March 4, 2002

Date of Receipt: March 5, 2002

This supplement has been submitted to support the use of ARIMIDEX in early breast cancer in postmenopausal women.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 3, 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be September 5, 2002.

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). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within approximately 120 days of receipt of your pediatric drug development plan, we will review your plan and notify you of its adequacy.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit

a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will make a determination whether to grant or deny a request for a waiver of pediatric studies during the review of the application. In no case, however, will the determination be made later than the date action is taken on the application. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

Under 21 CFR 314.102(c) of the new drug regulations, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Alternatively, you may choose to receive such a report by telephone.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Oncology Drug Products, HFD-150
Attention: Division Document Room
NUMBER
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Oncology Drug Products, HFD-150
Attention: Division Document Room
NUMBER
1451 Rockville Pike
Rockville, Maryland 20852-1420

If you have any questions, call Amy Baird, Consumer Safety Officer, at (301) 594-5771.

Sincerely,

{See appended electronic signature page}

/S/

Dotti Pease
Chief, Project Management Staff
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Amy Baird
4/2/02 02:36:47 PM
for Dotti Pease