



NDA 20-541/S-016

AstraZeneca Pharmaceuticals LP
Attention: E. Jane Valas, Ph.D.
Associate Director, Regulatory Affairs
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Dr. Valas:

Please refer to your supplemental new drug application dated November 18, 2004, received November 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ARIMIDEX7 (anastrozole) Tablets.

We acknowledge receipt of your submissions dated May 4 and September 6, 2005.

This supplemental new drug application provides the updated report of the ATAC data as requested in a subpart H commitment associated with the approval of supplemental application 010.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-541/S-016.**" Approval of this submission by FDA is not required before the labeling is used.

We approved this supplemental NDA (S-010) under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills your commitment made under 21 CFR 314.510.

In addition, we note your following post-marketing commitments, which were part of the original subpart H post-marketing commitments for S-010 and which are specified in your submission dated September 15, 2005, have been revised to be non Subpart H post-marketing commitments. These commitments, along with any completion dates agreed upon, include:

1. To conduct a double-blind, randomized comparison trial using Arimidex with and without bisphosphonate therapy in early breast cancer patients. The trial entitled "A multi-center phase III/IV study of the effects of risendronate sodium on bone, in postmenopausal

women, with hormone-receptor positive early breast cancer, treated with anastrozole with either high-risk of fragility fracture (open-label, non comparative stratum), or moderate risk of fragility fracture (randomized, double-blind stratum), and the effects of anastrozole on bone in post-menopausal women with hormone-receptor positive early breast cancer and low-risk of fragility fracture (open-label, non-comparative stratum)" is ongoing.

Final Report Submission: 12 month data- 4th quarter 2007 (results of hyperlipidemia substudy)
24 month data - 4th quarter 2008

2. To continue to collect data in the ATAC trial on serious adverse events (SAEs) including fractures and those SAEs associated with hypercholesterolemia (i.e., cardiovascular and cerebrovascular adverse events) for an additional five years following discontinuation of treatment or breast cancer recurrence. Submit the safety report summarizing these data by January 1, 2011.

In addition, you have agreed to the following post-marketing commitment.

3. To submit a final analysis of overall survival at a median follow-up of 10 years on the ATAC trial.

Final Report Submission: January 1, 2011

Please submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send 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, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Amy Baird, Consumer Safety Officer, at (301) 594-5779.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Acting Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Robert Justice
9/16/2005 07:17:36 PM