DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-541/S-024 and S-025

AstraZeneca
Attention: E. Jane Valas, Ph.D.
1800 Concord Pike, PO Box 8355
Wilmington, DE 19803-8355

Dear Dr. Valas:

Please refer to your supplemental new drug application dated July 1, 2008, received July 1, 2008, (S-024) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arimidex (anastrozole) Tablets which provided for: 1) the final study report (12 month data) of a double blind, randomized comparison of Arimidex with and without bisphosphonate therapy in early breast cancer patients and results of the hyperlipidemia substudy, and 2) the final study report (24 month data) results of a double blind, randomized comparison of Arimidex with and without bisphosphonate therapy in early breast cancer patients.

We acknowledge receipt of your submissions dated July 27, 2007, January 27, February 9, February 18, March 31, April 27, and April 30, 2009.

We also refer to your supplemental new drug application dated January 21, 2009, received January 21, 2009, (S-025), which provided for revising the package insert to include the following adverse events: alopecia, trigger finger, and carpal tunnel syndrome.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for package insert submitted April 30, 2009). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-541/S-024 and S-025."

In addition, 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, Division of Drug Oncology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road

Beltsville, MD 20705-1266

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
Food and Drug Administration
Suite 12B05
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).

If you have any questions, call Alice Kacuba, Chief, Project Management Staff, at (301) 796-1381.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, M.D.
Deputy 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/

Ann Farrell

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