DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-541/SLR-020/SLR-021/SLR-023

AstraZeneca Pharmaceutical LP
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 applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arimidex® (anastrozole) Tablets.

SLR	Letter date	Received date	Regulatory due date	Provides for	Type
SLR-020	February 23, 2007	February 23, 2007	August 23, 2007	Adverse Events (clarifying ischemic cardiovascular events and adding carpal tunnel events)	Changed Being Effected
SLR-021	July 16, 2007	July 16, 2007	January 16, 2008	Adverse Events-Post-Marketing (hepatobiliary events)	Changed Being Effected
SLR-023	November 29, 2007	November 29, 2007	May 29, 2008	Conversion to PLR	Prior Approval

We acknowledge receipt of your November 4, 2008 submission to SLR-023.

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 the package insert, test for patient package insert. 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/SLR-020/SLR-021/SLR-023."

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}

Robert Justice. M.D.
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

12/10/2008 06:18:20 PM