DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-541/S-015

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 6, 2003, received November 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ARIMIDEX® (anastrozole) Tablets.

We also refer to your amendment of August 16, 2004, received August 17, 2004.

This supplemental new drug application provides for inclusion of language in the package insert relative to premenopausal women; inclusion of language on possible bone mineral density (BMD) reduction; inclusion of BMD language in the **PRECAUTIONS-Laboratory Tests** section; and inclusion of hypersensitivity reactions in the **ADVERSE REACTIONS** section.

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 enclosed labeling text.

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

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-541/S-015". Approval of this submission by FDA is not required before the labeling is used.

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).

If you have any questions, call Amy Baird, Project Manager, at (301) 594-5779.

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

Enclosure