



NDA 17-970/S-054

AstraZeneca Pharmaceuticals LP  
1800 Concord Pike  
P.O. Box 8355  
Wilmington, DE 19803-8355

Attention: E. Jane Valas, Ph.D.  
Associate Director, Regulatory Affairs

Dear Dr. Valas:

Please refer to your supplemental new drug application dated May 9, 2005, received May 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NOLVADEX® (tamoxifen citrate) Tablets.

We acknowledge receipt of your submissions dated September 29, 2005, and March 6, 2006.

This supplemental new drug application provides for revisions to the package insert based on data from the ATAC trial for Arimidex® (anastrozole) Tablets.

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 and patient 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 17-970/S-054.**" Approval of this submission by FDA is not required before the labeling is used.

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. We are waiving the pediatric study requirement for this application.

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

the Division of Drug Oncology Products and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
Food and Drug Administration  
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  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Christy Cottrell, Consumer Safety Officer, at (301) 796-1347.

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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Robert Justice  
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