



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-753/S-006

Pfizer Inc.
235 East 42nd Street
New York, NY 10017-5755

Attention: Ann Carey, Director
U.S. Regulatory Affairs

Dear Ms. Carey:

Please refer to your supplemental new drug application dated December 8, 2004, received December 9, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aromasin® (exemestane) Tablets, 25 mg.

We acknowledge receipt of your submissions dated January 28, February 23, April 4, May 6, May 10, June 20, July 15, July 20, and August 15, 2005.

This supplemental new drug application provides for the use of Aromasin® (exemestane) Tablets, 25 mg for adjuvant treatment of postmenopausal women with estrogen-receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to AROMASIN® for completion of a total of five consecutive years of adjuvant hormonal therapy.

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) for S-006 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 20-753/S-006.**" 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.

We remind you of your postmarketing study commitment in your submission dated September 30, 2005. This commitment is listed below.

- Submit an analysis of overall survival after 10 years of follow-up for IES.
Final Report Submission: by 4Q2011

Please submit the analysis to your NDA for this product. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of your commitment in your annual report to this NDA. The status summary should include expected summary completion and a final report submission date and any changes in plans since the last annual report. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **“Postmarketing Study Commitment Final Report”**, or **“Postmarketing Study Commitment Correspondence.”**

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 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).

If you have any questions, call Brenda Atkins, Regulatory Project Manager, at (301) 594-5767.

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
10/5/2005 11:11:46 AM