DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-753/S-007

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

Attention: Ms. Natalie Touzell, Director
U.S. Regulatory Affairs

Dear Ms. Touzell:

Please refer to your supplemental new drug application dated October 26, 2006, received October 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aromasin® (exemestane) Tablets, 25 mg.

We acknowledge receipt of your submission dated December 16, 2008.

This supplemental new drug application provides for a Patient Package Insert (PPI) for Aromasin.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon PPI text.

The final printed PPI must be identical to the enclosed PPI submitted December 16, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of the PPI [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 PPI submitted December 16, 2008. 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 20-753/S-007**."

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, Regulatory Project Manager, at (301) 796-4256.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure - Patient Package Insert (December 2008)

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

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