



NDA 20-753/S-005

Pfizer Inc.  
Regulatory Affairs  
235 E. 42nd Street  
New York City, NY 10017-5755

Attention: Kristina D. Spranger  
Senior Manager, US Regulatory Affairs

Dear Ms. Spranger:

Please refer to your supplemental new drug application dated March 22, 2004, received March 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aromasin® (exemestane tablets).

This supplemental new drug application provides for revisions to the **Carcinogenesis, Mutagenesis, Impairment of Fertility** subsection of the **PRECAUTIONS** section of the package insert based upon a Safety Assessment regarding exemestane carcinogenesis, which evaluated the results of two carcinogenicity studies (Studies 6538 and 6539) and two supportive studies.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text. In addition, we acknowledge the final printed labeling (FPL) submitted on August 16, 2004. This FPL will be retained with your files.

The final printed labeling (FPL) for S-005 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 20-753/S-005." 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 Brenda Atkins, Regulatory Project Manager, at (301) 594-5767.

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 – Labeling

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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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Grant Williams  
9/23/04 03:38:48 PM  
for Dr. Pazdur