DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-726/S014

Novartis Pharmaceutical Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Attention: Arlene Wolny, PhD
Director, Drug Regulatory Affairs

Dear Dr. Wolny:

Please refer to your supplemental new drug application dated December 18, 2006, received December 20, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Femara (letrozole tablets).

This "Changes Being Effected" supplemental new drug application provides information to the package insert to strengthen the pregnancy warning and adds additional adverse event information. The following sections contained proposed additions: **CONTRAINDICATIONS, WARNINGS** (Pregnancy subsection), **ADVERSE EVENTS** (First and Second Line subsection). This submission was received electronically as Changes Being Effected 0 (CBE-0) with Final Printed Label and Structured Product Labeling (SPL).

We have completed our review of this supplemental application. This application is approved, effective on the date of this letter, for use as recommended in the Final Printed Labeling (FPL) submitted on December 18, 2006.

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 Janet Jamison, Regulatory Project Manager, at (301)796-2313.

Sincerely,

{See appended electronic signature page}

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

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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