



NDA 20-726/S-013

Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg. 105/Rm 2W200
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 November 29, 2005, received December 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Femara (letrozole) Tablets, 2.5 mg.

We acknowledge receipt of your submission dated May 10, 2006.

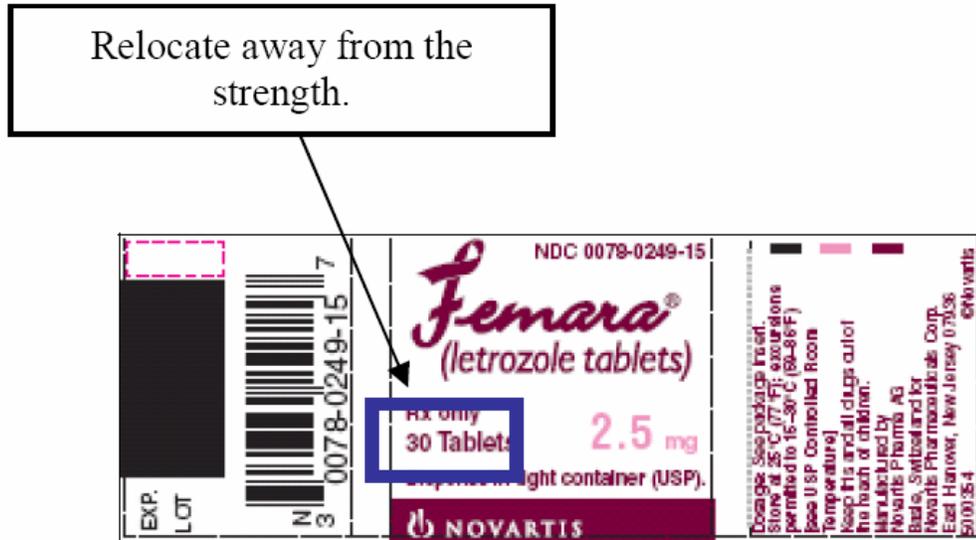
This supplemental new drug application provides for a change in the outer label of the container packaging.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 10, 2006.

However, we have the following comments.

1. We recommend the removal of the decorative logo (breast cancer ribbon) that appears on the first letter of the proprietary name. This gives the appearance of a cursive font style to the proprietary name and makes it difficult to read. The logo also distracts from the product name. In addition, the ribbon at the top of the letter "F" may be misinterpreted as the letters "J", "T" or "L" which can increase the potential for medication errors. Please revise the font size and font style to improve readability.
2. In order to decrease clutter and improve readability, relocate the statement "Dispense in tight container (USP)" from the front panel to the side of the label and move the "Rx only" statement to the bottom third of the label.
3. The light pink color used for the strength is difficult to read. Revise the color to improve the readability of the strength.
4. Postmarketing experience has shown that medication errors have occurred due to confusion of the net quantity for the product strength when the net quantity is in close proximity or appears

more prominent. Thus, we request relocation of the net quantity statement so that it is not in close proximity of the strength and removal of the bold type from the strength to decrease its prominence.



5. Ensure that all Unit-of-Use bottles (i.e., 30 count) will have a Child Resistant Closure to be in accordance with the Poison Prevention Act.
6. Increase the prominence of the statement “Physician Sample- Not for Sale” and relocate the statement above the proprietary name.

Please submit the above changes as a “Changes Being Effected” (CBE-0) supplement. Approval of this submission by FDA is not required before the labeling is used.

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ann Staten, Regulatory Project Manager, at (301) 796-1468.

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Ann Farrell
6/26/2006 08:14:52 AM
Farrell for Justice