



NDA 20-726/SLR-017

Novartis Pharmaceuticals Corporation  
Attention: Harinder Dhillon, Pharm. D  
Associate Director, Drug Regulatory Affairs  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Ms. Dhillon:

Please refer to your supplemental new drug application dated June 2, 2008, received June 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Femara® (letrozole tablets). Please also refer to the FDA electronic correspondence of July 28, 2008 and your electronic correspondence response of August 1, 2008.

This prior approval supplemental new drug application provides for revision of the “Post-marketing Experiences” subsection of the ADVERSE REACTIONS section of the package insert to include rare cases of angioedema and anaphylactic reactions reported since approval. This submission was received electronically as Labeling Supplement- Prior Approval with final printed label (FPL) 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 enclosed agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert).

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  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, please 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

Enclosure

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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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Robert Justice  
8/7/2008 02:29:54 PM