DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-726/S-024

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Concetta Freund
Drug Regulatory Affairs
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Ms. Freund:

Please refer to your Supplemental New Drug Application (sNDA) dated August 10, 2011, received August 10, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Femara® (letrozole) Tablets 2.5 mg.

We acknowledge receipt of your amendments dated October 28, 2011 and December 19, 2011.

This "Prior Approval" supplemental new drug application proposes updates to the ADVERSE REACTIONS section of the labeling to include carpal tunnel syndrome and trigger finger. In addition, this supplement proposes to add birth defects to the USE IN SPECIFIC POPULATIONS section of the package insert.

We have completed our review of this supplemental application, as amended. It is approved for the updates in the ADVERSE REACTIONS section to include carpal tunnel syndrome and trigger finger, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. It is not approved for the birth defects language in USE IN SPECIFIC POPULATIONS.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

1155-5 Complete study CFEM345D2407: A study of an open-label, randomized, multi-center study to evaluate the skeletal and lipid profile effects of letrozole and tamoxifen in postmenopausal women with resected, hormone receptor positive breast cancer.

The timetable you submitted on April 27, 2010, states that you will conduct this study according to the following schedule:

a. Two-year data will be provided in the 2008 BIG 1-98 annual report
b. Last patient last visit for CFEM345D2407 is March 2011.
c. Submit the final CFEM345D2407 study report in Q4 2011.

REPORTING REQUIREMENTS

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 Theresa Ferrara, Regulatory Project Manager, at (301) 796-2848.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

AMNA IBRAHIM
12/23/2011