DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021344/S-018

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
US Agent for AstraZeneca UK Limited
Attention: Nicholas J. Troise
1800 Concord Pike, PO Box 8355
Wilmington, DE 19803-8355

Dear Mr. Troise:

Please refer to your Supplemental New Drug Application (sNDA) dated December 12, 2011, received December 12, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Faslodex® (fulvestrant) Injection.

We also refer to our May 30, 2012 letter notifying you that the labeling supplement was administratively split into two labeling supplements; S-018 and S-019.

This "Changes Being Effected" supplemental new drug application provides for revisiting the package insert, Section 6.2 Post-Marketing Experience to add "elevation of bilirubin, elevation of gamma GT, hepatitis, and liver failure have been reported infrequently (<1%)."

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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).

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 Alice Kacuba, chief, Project Management Staff, at (301) 796-1381.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
Office of Hematology & 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
07/13/2012