



NDA 021344/S-031

**SUPPLEMENT APPROVAL**

AstraZeneca Pharmaceuticals LP  
Attention: Jamie L. Austin, PhD, RAC  
Regulatory Affairs Director  
200 Orchard Ridge Drive  
Gaithersburg, MD 20878

Dear Dr. Austin:

Please refer to your Supplemental New Drug Application (sNDA) dated August 30, 2016, received August 30, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FASLODEX<sup>®</sup> (fulvestrant) Solution for Injection, 250 mg/5 ml.

This “Changes Being Effected” supplemental new drug application proposes updates to the instructions and pictures on the carton and container labeling to match the Full Prescribing Information that was approved for NDA 021344 Supplement 027.

**APPROVAL & LABELING**

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.

**CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your August 30, 2016, and October 25, 2016 submissions containing final printed carton and container labels.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion (OPDP)  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **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 Charlene Wheeler, MSHS, Senior Regulatory Project Manager, at (301) 796-1141.

Sincerely,

*{See appended electronic signature page}*

Geoffrey Kim, MD  
Director  
Division of Oncology Products 1  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURE:  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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CHARLENE N WHEELER  
10/26/2016

GEOFFREY S KIM  
10/26/2016