

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21344/S-029

Trade Name: FASLODEX

Generic or Proper Name: fulvestrant solution for injection, 250 mg/5 ml

Sponsor: AstraZeneca Pharmaceuticals LP

Approval Date: July 12, 2016

Indication: To update the Dosage and Administration, Warnings and Precautions, and Adverse Reactions sections of the Full Prescribing Information regarding the risk of severe injection site related neurological events

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APPROVAL LETTER



NDA 021344/S-029

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
Attention: Jamie L. Austin, PhD, RAC
Regulatory Affairs Director, Oncology
One MedImmune Way
Gaithersburg, MD 20878

Dear Dr. Austin:

Please refer to your Supplemental New Drug Application (sNDA) dated April 28, 2016, received April 28, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FASLODEX[®] (fulvestrant) Solution for Injection, 250 mg/5 ml.

This Prior Approval supplemental new drug application proposes to update the Dosage and Administration, Warnings and Precautions, and Adverse Reactions sections of the Full Prescribing Information regarding the risk of severe injection site related neurological events.

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.

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, text for the patient 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 that includes labeling changes 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).

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.

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(S):
Content of Labeling

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