



NDA 20498/S-027

**SUPPLEMENT APPROVAL**

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

Dear Dr. Austin:

Please refer to your Supplemental New Drug Application (sNDA) dated September 20, 2016, received, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Casodex® (bicalutamide) tablets).

This Prior Approval supplemental new drug application proposes the following changes for Casodex: possible antiandrogen therapy induced sperm morphological changes and use of adequate contraception during and for 130 days after Casodex therapy and the conversion to Pregnancy and Lactation Labeling Rule (PLLR) format.

**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 and 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 include 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).

### **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 Christina Marshall, Safety Regulatory Project Manager, at (301) 301-796-3099.

Sincerely,

*{See appended electronic signature page}*

Katherine Fedenko, MS, CRNP  
Deputy Director for Safety  
Division of Oncology Products 1  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

### **ENCLOSURES:**

Content of Labeling  
Patient Package Insert

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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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KATHERINE M FEDENKO  
03/17/2017