



NDA 019726/S-056, 057
NDA 020578/S-034, 035

SUPPLEMENT APPROVAL

AstraZeneca
Attention: E. Jane Valas, Ph.D.
Associate Director, Regulatory Affairs
1800 Concord Pike
PO Box 8355
Wilmington, DE 19803-8355

Dear Dr. Valas:

Please refer to your Supplemental New Drug Applications (sNDA) dated December 7 and 17, 2012, received December 7 and 17, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zoladex® (goserelin acetate) Implant, 3.6 mg and 10.8 mg.

We acknowledge receipt of your amendments dated December 20, 2012, March 22, April 5, and 16, 2013.

The Changes Being Effected and Prior Approval supplemental new drug applications provide for the following:

The supplemental applications, NDA 019726/S-056 and NDA 020578/S-034, submitted as a Changes Being Effected (CBE) supplements, propose adding information about mood swings and acne to the Post-Marketing section in ADVERSE REACTIONS.

The supplemental applications, NDA 019726/S-057 and NDA 020578/S-035, submitted as Prior Approval (PAS) supplements, propose adding convulsions to the Post-Marketing section in ADVERSE REACTIONS as requested in FDA's Supplement Request letter dated November 16, 2012.

We have completed our review of the supplemental applications, as amended. They are 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 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).

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 Amy Tilley, Regulatory Project Manager, at (301) 796-3994.

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:
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
06/18/2013