DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19732/S-041
NDA 20517/S-036

SUPPLEMENT APPROVAL

Abbvie Inc.
Attention: Gennadiy Koev, Ph.D.
Manager, Regulatory Affairs
1 North Waukegan Road
Dept. PA77, Building AP30
North Chicago, IL 60064

Dear Dr. Koev:

Please refer to your Supplemental New Drug Application (sNDA)s, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lupron Depot® (leuprolide acetate for depot suspension) Injection 7.5 mg, 22.5 mg, 30 mg, and 45 mg.

NDA/SLR #	Type	Letter date	Receipt date	Provides for
19732/S-041	PAS	December 20, 2013	December 20, 2013	Update the Lupron Depot 7.5 mg insert to comply with the labeling format requirements of the Physician's Labeling Rule (PLR).
20517/S-036	PAS	December 20, 2013	December 20, 2013	Combine the Lupron Depot 7.5 mg insert with the Lupron Depot 22.5 mg, 30 mg, and 45 mg insert into a single insert.

We acknowledge receipt of your amendments.

NDA/SLR #	Letter date of amendment	Receipt date of amendment
19732/S-041	May 23, 2014	May 23, 2014
20517/S-036	May 23, 2014	May 23, 2014
19732/S-041	April 28, 2014	April 28, 2014
20517/S-036	April 28, 2014	April 28, 2014

APPROVAL & LABELING

We have completed our review of this supplemental application, 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).

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:

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

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, Regulatory Project Manager, at (301) 796-1141.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Acting Division 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
06/27/2014