



NDA 019732/SLR-040
NDA 020517/SLR-035
NDA 019732

**SUPPLEMENT APPROVAL
SUPPLEMENT REQUEST**

AbbVie Endocrine, Inc.
Attention: Gennadiy Koev, PhD
Manager, Regulatory Affairs
1 N. Waukegan Road
Dept. PA77/Bldg. AP30-1
North Chicago, IL 60064

Dear Dr. Koev:

Please refer to the following table for your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA):

NDA NUMBERS	019732	020517
SUPPLEMENT NUMBERS	SLR-040	SLR-035
PRODUCT NAME	Lupron Depot (Leuprolide Acetate for Depot Suspension) 1M 7.5 mg	Lupron Depot (Leuprolide Acetate for Depot Suspension) 3M 22.5 mg, 4M 30 mg, and 6M 45 mg
DATE OF SUBMISSION	January 9, 2013	January 9, 2013
DATE OF RECEIPT	January 10, 2013	January 10, 2013

We acknowledge receipt of your amendments dated February 7, 2013 and May 28, 2013.

These “Prior Approval” supplemental new drug applications provides for:

NDA	Supp #	Provides for	Labeling Format
019732	040	<ul style="list-style-type: none"> Updating the Precautions section to include a “Convulsions” subsection Updating the Adverse Reactions section to include a “Postmarketing” subsection Updating the Adverse Reactions section by revising the following symptom to state: “Hepato-biliary disorder: Serious drug-induced liver injury.” 	Non-PLR
020517	035	<ul style="list-style-type: none"> Updating the Highlights section to add “Convulsions” to “Warnings and Precautions (5.5)” under “RECENT MAJOR CHANGES” Updating the Highlights section to add a bullet discussing “Convulsions” under “Warnings and Precautions” 	PLR

		<ul style="list-style-type: none">• Updating the Highlights section to revise subsection 6.4 under “Adverse Reactions” to state the following, “In postmarketing experience, mood swings, depression, rare reports of suicidal ideation and attempt, rare reports of pituitary apoplexy, and rare reports of serious drug-induced liver injury have been reported. (6.4)”• Updating the Full Prescribing Information to add subsection “5.5 Convulsions” to the “Warnings and Precautions” section• Updating the Full Prescribing Information to add subsection “6.4 Postmarketing” to the “Adverse Reactions” section• Updating the Adverse Reactions section of the Full Prescribing Information by revising the following symptom to state: “Hepato-biliary disorder: Serious drug-induced liver injury.”	
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We have completed our review of this supplemental application, as amended. 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), 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).

SUPPLEMENT REQUEST FOR PLR FORMAT

We request that you submit a supplement that provides for converting NDA 019732 to PLR format. While this is not mandatory, it would be helpful to healthcare prescribers if both package inserts for NDA 019732 and NDA 020517 were in the same format (PLR).

Submit draft labeling as a prior approval supplement to this application, incorporating all revisions since the last approval of the package insert. 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 also include annotations that support all proposed changes, including annual reportable changes. Your supplement must include updated content of labeling [21 CFR 314.50(1)(1)(i)]/[21 CFR 601.14(b)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

The supplement should be submitted within 90 days.

If you have any questions, call Rajesh Venugopal, Regulatory Project Manager, at (301) 796-4730.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Deputy Division Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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
07/10/2013