NDA 020011/S-046
NDA 019943/S-039

SUPPLEMENT APPROVAL

AbbVie Endocrinology Inc.
Attention: Pei Miao
Associate Director, Regulatory Affairs, Global Regulatory Strategy
1 N. Waukegan Road
Dept. PA72/Bldg. AP30
North Chicago, IL 60064

Dear Mr. Miao:

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

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 020011/S-046	Lupron Depot 3.75 mg (leuprolide acetate for depot suspension) for injection	July 29, 2022	July 29, 2022
NDA 019943/S-039	Lupron Depot 3.75 mg (leuprolide acetate for depot suspension) for injection	July 29, 2022	July 29, 2022

These "Changes Being Effected" supplemental new drug applications provide for labeling changes as specified in the Agency's supplement request letter dated July 12, 2022.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 prescribing information) 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via 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 these supplemental applications, 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 Olubusola Baoku, Regulatory Business Process Manager, at (301) 796 - 0191.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling – Prescribing Information

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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