NDA 019943/ S-040 and S-041
NDA 020011/ S-047 and S-048 **SUPPLEMENT APPROVAL**

AbbVie Endocrinology Inc.
Attention: Chelsea Li, MS, RAC
Sr. Manager, Global Regulatory Strategy
100 Park Avenue
Florham Park, NJ, 07932

Dear Chelsea Li:

Please refer to your supplemental new drug applications (sNDAs) dated October 17, 2023, and February 21, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lupron Depot (leuprolide acetate for depot suspension).

These Changes Being Effected sNDAs provide for:

1. the addition of Severe Cutaneous Adverse Reactions (SCARs), including erythema multiforme (EM), to the Warnings and Precautions and/or the Adverse Reactions sections of the approved Lupron Depot Prescribing Information

2. update to the prescribing information to include injection site necrosis as a postmarketing adverse reaction.

APPROVAL & LABELING

We have completed our review of these 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 FDA.gov.[1] 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental applications, you are exempt from this requirement.

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, contact Maria Wasilik, Senior Regulatory Project Manager, at 301-796-0567 or maria.wasilik@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Urology, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

[2] We update guidance documents periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at: https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARIA R WASILIK
09/10/2025 01:40:39 PM

AUDREY L GASSMAN
09/10/2025 01:41:32 PM