NDA 020263/S-054

SUPPLEMENT APPROVAL

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

Dear Pei Miao:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 14, 2023, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lupron Depot-PED (leuprolide acetate for depot suspension).

This "Changes Being Effected" supplemental new drug application provides for revisions to the container labels in alignment with labeling changes approved in Supplement 053.

APPROVAL & LABELING

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.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020263/S-054.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, 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 Oluwafunmike (Funke) Ajomale, Regulatory Business Process Manager, at oluwafunmike.ajomale@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

Enclosure(s):

Carton and Container Labeling

Hasmukh Patel

Digitally signed by Hasmukh Patel
Date: 12/04/2023 11:13:15AM
GUID: 508da71e00029e3864a0ad90c32d1866
Comments: Signed for Ramesh Raghavachari, Ph.D.