NDA 213388/S-005

SUPPLEMENT APPROVAL

AbbVie, Inc.
Attention: Aurora Cazares
Director, Business Services and Operations
1 N Waukegan Road
North Chicago, IL 60064

Dear Ms. Cazares:

Please refer to your Supplemental New Drug Application (sNDA) dated May 2, 2023, received May 2, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules).

We also refer to our approval letter dated July 30, 2024, which contained the following error: the enclosed blister pack was incorrect.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain July 30, 2024, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for an alternative simpler packaging configuration for Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules).

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 carton and container labels submitted on June 14, 2023, and June 7, 2024, 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 213388/S-005.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Stephanie Ngan, Regulatory Business Process Manager, at (240) 402 - 5932.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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