NDA 210450/S-004
NDA 210450/S-005
NDA 210450/S-006

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

AbbVie, Inc.
Attention: Glen Spears, Ph.D.
Director, Regulatory Affairs
1 N. Waukegan Road
Dept. PA72/Bldg. AP30-4
North Chicago, Illinois 60064

Dear Dr. Spears:

Please refer to your supplemental new drug applications (sNDAs) dated April 7, 8, and September 18, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Orilissa (elagolix sodium).

These Prior Approval supplemental new drug applications provide for the following changes:

S-004
Revisions to reflect the results of Study M18-980, a drug-drug interaction (DDI) study to assess the co-administration of a combined oral contraceptive (containing ethinyl estradiol and levonorgestrel) with elagolix 200mg twice daily. Study M18-890 also addressed postmarketing requirement (PMR) 3390-3.

S-005
Revisions to incorporate the results of Study M16-850, a DDI study to evaluate the effect of multiple doses of elagolix 300 mg twice daily on bupropion.

S-006
Revisions of relevant sections of the Orilissa Prescribing Information (PI) to align with the PI for Oriahnn (NDA 213388).

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 and Medication Guide), 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 *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 applications, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated, April 7, 2020, containing the final clinical study report for Study M18-980, conducted to address the following postmarketing requirement listed in the July 23, 2018, approval letter.

3390-3 A drug-drug interaction trial to assess the pharmacokinetics, safety, and tolerability of the co-administration of a combined oral contraceptive (containing ethinyl estradiol and levonorgestrel) with Orilissa 200 mg twice daily.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements and a postmarketing commitment listed in the July 23, 2018, approval letter that are still open.

PROMOTIONAL MATERIALS

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

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 Maria Wasilik, Regulatory Project Manager, at 301-796-0567.

Sincerely,

{See appended electronic signature page}

Christine P. Nguyen, M.D.
Director
Division of Urology, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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
02/01/2021 10:19:47 AM

CHRISTINE P NGUYEN
02/01/2021 11:34:56 AM