NDA 214846/S-007

SUPPLEMENT APPROVAL

Sumitomo Pharma Switzerland GmbH
c/o Sumitomo Pharma America, Inc.
Attention: Sejal Emerson, Pharm.D.
Senior Director, Regulatory Affairs
84 Waterford Drive
Marlborough, MA 01752

Dear Dr. Emerson:

Please refer to your supplemental new drug application (sNDA) dated June 30, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Myfembree (relugolix, estradiol, and norethindrone acetate) tablets.

This Prior Approval supplemental new drug application provides for an update to the prescribing information based on data from study MVT-601-3103, titled "SPIRIT EXTENSION: An International Phase 3 Open-Label, Single-Arm, Safety and Efficacy Extension Study to Evaluate Relugolix Co-Administered with Low-Dose Estradiol and Norethindrone Acetate in Women with Endometriosis-Associated Pain." The changes that were proposed are to update the following sections:

Section 1.3 (INDICATIONS AND USAGE: LIMITATIONS OF USE)
Section 2.2 (RECOMMENDED DOSAGE)
Section 6 (ADVERSE REACTIONS)

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, with updates to Section 6 (ADVERSE REACTIONS), 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

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

Prescribing Information, Patient Package Insert), 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.

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

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.

We are waiving the pediatric study(ies) requirement for this application because necessary studies are impossible or highly impracticable.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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.

If you have any questions, call Maria Wasilik, Senior Regulatory Project Manager, at 301-796-0567.

Sincerely,

{See appended electronic signature page}

Christina Chang, M.D., M.P.H.
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
  - Patient Package Insert

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
04/30/2024 02:30:11 PM

AUDREY L GASSMAN
04/30/2024 03:45:46 PM
Signing for Christina Chang, Division Director