NDA 204516/S-009
NDA 204516/S-014

SUPPLEMENT APPROVAL

Legacy Pharma Inc.
c/o G&L Scientific, Inc.
Attention: Gloria Kulcheski
U.S. Agent, Legacy Pharma Inc.
7 Giralda Farms
1st floor, Suite 120
Madison, NJ 07940

Dear Gloria Kulcheski:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 25, 2019, and August 14, 2024, and your amendments, submitted under section 505(b)) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Brisdelle (paroxetine) capsules.

These Prior Approval sNDAs provide for:

S-009: Revisions to the Prescribing Information and Medication Guide labeling to comply with the Pregnancy and Lactation Labeling Rule requirements.

S-014: Revisions to the Prescribing Information for consistency with labeling format regulations and guidance documents and for consistency with other paroxetine product labeling in response to our July 3, 2024, Prior Approval Supplement Request letter

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

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

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 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).

[2] We update guidance documents 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 Samantha Bell, Regulatory Project Manager, at (301) 796-9687.

Sincerely,

{See appended electronic signature page}

Aisha Johnson, MD, MPH, MBA
Deputy Director for Safety (Acting)
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

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/

AISHA P JOHNSON
02/11/2025 10:13:54 AM