



NDA 211616/S-022

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SUPPLEMENT APPROVAL

Esperion Therapeutics, Inc.
Attention: Satish Nachaegari
Vice President, Global Regulatory Affairs
3891 Ranchero Drive, Suite 150
Ann Arbor, MI 48108

Dear Satish Nachaegari:

Please refer to your supplemental new drug applications (sNDAs) dated and received January 21, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexletol (bempedoic acid) tablets.

Supplement 22

This Prior Approval sNDA provides for changes to the Nexletol Prescribing Information to remove Section 8.6 *Renal Impairment* and update Section 12.3 *Pharmacokinetics* based on the results of trial 1002-071, titled, *A Phase 1, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics of Bempedoic Acid in Healthy Subjects With Normal Renal Function and Subjects With End-Stage Renal Disease Receiving Hemodialysis*.

The Patient Package Insert was revised to reflect the changes in the Prescribing Information.

Supplement 23

This Prior Approval sNDA provides for changes to the Nexletol Prescribing Information to update Section 8.2 *Lactation* based on the results of study 1002FDC-075, titled, *An Open- Label Postmarketing Milk-Only Lactation Study to Evaluate the Concentration of Bempedoic Acid and Bempedoic Acid and Ezetimibe in the Breast Milk of Healthy Lactating Women Administered Therapeutic Doses of Bempedoic Acid or Bempedoic Acid/Ezetimibe Fixed Combination Drug Product (FCDP)*.

The Patient Package Insert was revised to reflect the changes in the Prescribing Information.

This sNDA was submitted to address the following postmarketing requirement (PMR) listed in the February 21, 2020, approval letter:

- 3797-4 Perform a lactation study (milk only) in lactating women who have received therapeutic doses of Nexletol (bempedoic acid) using a validated assay to

assess concentrations of bempedoic acid in breast milk and the effects on the breastfed infant.

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 Patient Package Insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (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

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>.

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.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated December 19, 2024, containing the final report for PMR 3797-4, cited above. We have reviewed the submission and conclude that the above requirement has been fulfilled.

We remind you that there are postmarketing requirements listed in the February 21, 2020, approval letter and September 20, 2024, postapproval postmarketing requirement letter that are still open.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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

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If you have any questions, contact Ron Picking, Regulatory Project Manager, at 240-402-3211 or ronald.pickingiii@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

John Sharretts, MD
Director
Division of Diabetes, Lipid Disorders, and Obesity
Office of Cardiology, Hematology, Endocrinology,
and Nephrology
Office of New Drugs
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/

JOHN M SHARRETTS
07/21/2025 08:58:03 AM