NDA 211616
NDA 211617

NOTIFICATION OF NON-COMPLIANCE WITH PREA

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

Dear Mr. Nachaegari:

Please refer to your new drug application (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Nexletol (bempedoic acid) tablets (NDA 211616), which was approved on February 21, 2020, and Nexlizet (bempedoic acid and ezetimibe) tablets (NDA 211617), which was approved on February 26, 2020.

The Agency has determined that you have failed to meet the postmarketing requirements (PMRs) of the Pediatric Research Equity Act (PREA) for these applications because you have not yet submitted your pediatric assessment for PMRs 3797-1 and PMR 3798-1, which were deferred until August 2022. Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDAs with a cross-reference letter to the investigational new drug application (IND) to which your protocol has been submitted.

If you have any questions, call Ron Picking, Regulatory Project Manager, at 240-402-3211.

Sincerely,

{See appended electronic signature page}

Monika Houstoun, Pharm.D., M.P.H.
Deputy Director for Safety
Division of Diabetes, Lipid Disorders, and Obesity
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

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/

MONIKA A HOUSTOUN
11/21/2022 04:41:04 PM