ESPERION | REACHING GOALS

26 December 2022

John Sharretts, M.D., Director
Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

RESPONSE TO PREA NON-COMPLIANCE LETTER:

DEFERRAL EXTENSION REQUESTED

Re: **NDA 211616, Serial No. 0367**
Nexletol® (bempedoic acid) tablets
Indication: Primary Hyperlipidemia

NDA 211617, Serial No. 0396
Nexlizet® (bempedoic acid/ezetimibe) tablets
Indication: Primary Hyperlipidemia

Dear Dr. Sharretts:

Reference is made to the New Drug Application (NDA) 211616 for Nexletol® (bempedoic acid 180 mg) tablets and NDA 211617 for Nexlizet® (bempedoic acid/ezetimibe) tablets, approved 21 February 2020 and 26 February 2020, respectively. Nexletol and Nexlizet are indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

Additional reference is made to the postmarketing study requirements (PMRs) 3797-1 and 3798-1 for NDAs 211616 and 211617, respectively, and to the PREA non-compliance letter from the Agency dated 21 November 2022 involving these PMRs.

Final reference is made to an email communication with the FDA with advice on response to the PREA non-compliance letter.

The purpose of this submission is to respond to the Agency's 21 November 2022 PREA non-compliance letter regarding PMRs 3791-1 and 3798-1. An explanation for the delay, as well as a request for deferral extension is included herein. We also understand the Agency has received our 26 October 2022 submission to NDAs 211616 and 211617 containing a revised timetable for completion of PMRs 3797-1, 3798-1, 3797-2, and 3798-2, which is presently under review.

Since program inception, Esperion has worked diligently to pursue clinical development of bempedoic acid in pediatric patients and remains committed to fulfilling existing PREA obligations. In working with the Agency to gain alignment on the PMR protocol design, develop a new pediatric friendly formulation, and navigate impact of the COVID-19 public health emergency on the pending trial, we have been transparent about the status of our program, having completed our draft and final protocol submissions on schedule and sharing further status

updates and projections in our previous two annual reports. Hence, rationale and new estimated timeframes for completion presented in Module 1.9.2 of this submission are consistent with our previous submission dated 26 October 2022. We acknowledge, however, that the 26 October 2022 submission was not prominently identified as a deferral extension request and apologize for this oversight. Based on the advice provided from the Division by email dated 08 December 2022, we herein provide a request for deferral extension.

The complete submission to this NDA includes the following documents:

- Cover Letter
- Form FDA 356h
- Request for Deferral Extension (Module 1.9.2)

If you have any questions or comments concerning this submission, please feel free to contact me directly at 734-478-7116, by facsimile at 734-887-3944, or by email at snachaegari@esperion.com.

Sincerely,

Satish K Nachaegari

Digitally signed by Satish K Nachaegari
Date: 2022.12.26 12:35:41 -07'00'

Satish Nachaegari,
Executive Director, Global Regulatory Affairs