DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Chris Norenberg
ESPERION Therapeutics, Inc.
3891 Ranchero Drive, Suite 150
Ann Arbor, MI 48108

**RE: NDA 211617**
NEXLIZET® (bempedoic acid and ezetimibe) tablets, for oral use
MA 598

Dear Chris Norenberg:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer connected TV (CTV) broadcast advertisement (US-NXZT-2500041-1) (TV ad) for NEXLIZET® (bempedoic acid and ezetimibe) tablets, for oral use (Nexlizet) submitted by ESPERION Therapeutics, Inc. (Esperion) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Nexlizet and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad includes the following claims and presentations (in pertinent part, emphasis original):

- **Voiceover (VO)**: "NEXLIZET may help. It contains the only nonstatin FDA approved..." (frame 6)

- **VO**: "...to lower bad cholesterol and reduce the risk of heart attack…"
  **SUPER**: "The bempedoic acid ingredient of NEXLIZET is the only nonstatin proven to reduce the risk of heart attack…" (frame 7)

- **VO**: "...in statin intolerant patients."
  **SUPER**: "…in patients who are unable to take recommended statin treatment." (frame 8)

- **VO**: "Can't take a statin? Make NEXLIZET happen."
  **SUPER**: "**CAN'T TAKE A STATIN? MAKE NEXLIZET HAPPEN.**" (frame 16)

These claims and presentations misleadingly suggest that bempedoic acid, a component of Nexlizet, is the only nonstatin "FDA approved to lower bad cholesterol and reduce the risk of heart attack in statin intolerant patients" and "proven to reduce the risk of heart attack in patients who are unable to take recommended statin treatment," when this is not the case. Specifically, certain PCSK9 inhibitors are also FDA approved to lower LDL cholesterol and

reduce the risk of major adverse cardiovascular events such as heart attack, and the indications for these products do not limit their use to adult patients who are either statin tolerant or intolerant.

In addition, the TV ad is misleading because of the compelling and attention-grabbing visuals (e.g., the numerous cartoon-like “lipid lurkers” entering and exiting the various scenes in an artery while swimming around and towards the viewer, diving, doing flips, collecting and sticking to arterial walls, and talking to one another in the “arterial environment” where blood is constantly flowing) during the presentation of the major statement, which interfere with the comprehension of the major statement.

**Conclusion and Requested Action**

For the reasons described above, the TV ad misbrands Nexlizet and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Esperion take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above).

Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Nexlizet that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Nexlizet.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 598 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6.

Additionally, the response submission should be coded as an Amendment to eCTD Sequence 0757 under NDA 211617. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ankur Kalola, PharmD, RAC
Regulatory Review Officer
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

{See appended electronic signature page}

Sapna Shah, PharmD
Team Leader
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

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**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.**

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/s/

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ANKUR S KALOLA
12/19/2025 12:43:25 PM

SAPNA SHAH
12/19/2025 12:45:22 PM