DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Peter Thomas, Director, Regulatory Affairs
SK Life Science, Inc.
461 From Rd.
Paramus, NJ 07562

RE: NDA 212839
Xcopri® (cenobamate tablets) for oral use, CV
MA 592

Dear Peter Thomas:

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 television advertisement (TV ad), titled "Road to Reduction XCOPRI DTC Commercial" for XCOPRI® (cenobamate tablets) for oral use, CV (Xcopri) submitted by SK Life Science, Inc. (SK Life Science) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Xcopri and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad is misleading because it includes claims and presentations about the uses and benefits of Xcopri, but completely omits the warning and precaution regarding liver injury from the WARNINGS AND PRECAUTIONS, Liver Injury section of the FDA-approved Prescribing Information.

Additionally, while the TV ad includes some risk information regarding the serious risks with Xcopri, it omits certain material information pertaining to these risks. Specifically, the TV ad fails to disclose information from the "**What is the most important information I should know about XCOPRI?**" section of the Medication Guide (MG) that use of Xcopri may cause serious side effects, including problems with the electrical system of the heart (QT shortening). We acknowledge that the TV ad includes the warning, "Serious, life threatening allergic reactions or rash can occur, which may affect the liver, other organs, body parts, or blood cells, as can problems with the heart", however this does not mitigate the misleading impression.

The TV ad is misleading because it fails to include material information in the major statement about the advertised drug in the manner required for TV ads for human prescription drugs. Specifically, information regarding hypersensitivity reactions is included only in the SUPERs. The TV ad fails to communicate in the audio that patients should tell their healthcare provider or get emergency help right away if they have symptoms of an

allergic reaction, as conveyed in the MG for Xcopri. Furthermore, the TV ad fails to communicate in the audio that patients should tell their healthcare provider right away if they have suicidal thoughts or actions.

The major statement includes presentations where the verbatim complete transcript or verbatim key terms or phrases from the corresponding audio do not appear in dual modality, along with presentations where there is information in the SUPERs that is not from the corresponding audio. Therefore, the TV ad is misleading because it fails to present the major statement concurrently using both audio and text (dual modality).

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Xcopri 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 SK Life Sciences 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 Xcopri that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Xcopri.

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 592 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 7127 under NDA 212839. 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}

Lindsay McCann, PharmD, BCCCP
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Taylor Burnett Mmagu, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

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/

LINDSAY M MCCANN
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TAYLOR B BURNETT MMAGU
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