DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Dr. Brenda Pillari
Head of Regulatory Affairs, North America
Viatris Specialty LLC
3711 Collins Ferry Road
Morgantown, WV 26505

RE: NDA 201688
TOBI® PODHALER® (tobramycin inhalation powder), for oral inhalation use
MA 931

Dear Dr. Brenda Pillari:

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 (DTC) video, titled "TOBI-2022-0131_V2 US_Misty (b) (6) Video 2 Jax's Experience with the TOBI PODHALER" (TOBI-2022-0131) (video) for TOBI® PODHALER® (tobramycin inhalation powder), for oral inhalation use (TOBI Podhaler) submitted by Viatris Specialty LLC (Viatris) under cover of Form FDA 2253. FDA has determined that the video is false or misleading. Thus, the video misbrands TOBI Podhaler and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The video includes statements such as the following (underlined emphasis added; in pertinent part):

> **Jax (patient)**
>
> VOICEOVER (VO): "The one thing I love about the TOBI Podhaler is when I am running late, I can do it on the way to school in the car."
>
> **Misty (parent)**
>
> VO: "My favorite things about the TOBI Podhaler are how portable it is, how quick it is to use, and how you can use it anywhere."
>
> VO: "We have used it on vacation, in the car, and while running out of the door on the way to school."

These claims create the misleading impression that patients can perform the administration process for TOBI Podhaler anywhere, such as "in the car" or "while running out of the door on the way to school," without concern. However, we note that the FDA-approved Instructions for Use (IFU) for TOBI Podhaler includes several detailed steps requiring adequate lighting and stable conditions to properly complete the preparation and

administration of the product. For example, the IFU states (bolded emphasis original; underlined emphasis added; in pertinent part):

- "**Wash and dry your hands**."
- "[H]old the base of the storage case and unscrew the lid...Set the lid aside."
- "Hold the body of the Podhaler device and unscrew the mouthpiece...Set the mouthpiece aside on a clean, dry surface."
- "Hold the used capsule up to the light and look through it. It should be empty with only a fine coating of powder remaining on the inside surface of the capsule...If the capsule **is not** empty, see "**What to do with a capsule that has not been emptied**""
- "Repeat Step 5 to Step 17 for 3 more times until your full dose (4 capsules) has been taken."

In addition, with respect to the storage and handling of TOBI Podhaler, the IFU states "Only peel back the foil from 1 capsule at a time and remove the capsule just before you are going to use it in the device because the blister protects the capsule from moisture," and the "**How should I store TOBI Podhaler?**" section of the IFU instructs patients to "**Keep the TOBI Podhaler capsules and Podhaler device in a dry place.**" (bolded emphasis original; in pertinent part). The misleading impression described above is concerning because actions that result in incomplete emptying of the capsule(s), or storage and handling conditions that expose the TOBI Podhaler device and/or capsules to moisture may reduce the amount of drug and result in a suboptimal dose of TOBI Podhaler being administered to the patient. We acknowledge that the video includes some information pertaining to the use of the TOBI Podhaler; however, this does not mitigate the misleading impression.

Conclusion and Requested Action

For the reasons described above, the video misbrands TOBI Podhaler 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 Viatris 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 TOBI Podhaler that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of TOBI Podhaler.

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 931 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 0495 under NDA 201688. 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}

Qumerunnisa Syed, PharmD
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Samuel Skariah, PharmD, RAC
Team Leader
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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.

/s/

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