DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

September 9, 2025

Yeasin Chowdhury
Director, Promotional Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilmington, DE 19803-8355

RE: STN 125020/3218
FLUMIST

Dear Yeasin Chowdhury:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, *2025 FluMist DTC Home Done Different 60s* direct-to-consumer (DTC) Broadcast Ad (US-85954) (TV ad) for FLUMIST®, submitted under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands FLUMIST, and makes its distribution in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). *See* 21 U.S.C. §§ 352(n), 321(n), & 331(a); *cf.* 21 CFR § 202.1(e)(1) & (e)(5).

Background

According to the FDA-approved prescribing information (PI) for FLUMIST:

FLUMIST is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUMIST is approved for use in persons 2 through 49 years of age.

FLUMIST is contraindicated in patients with a known hypersensitivity to any component of FLUMIST, including egg protein, or after a previous dose of any influenza vaccine. It also is contraindicated in children who are receiving aspirin therapy or aspirin-containing therapy because of the risk of Reye's Syndrome.

The Administration Instructions indicate that individuals 2 through 17 years of age should not self-administer FLUMIST.

WARNINGS AND PRECAUTIONS include, but are not limited to, Risks of Hospitalization and Wheezing in Children Younger than 24 Months of Age; Asthma, Recurrent Wheezing and Active Wheezing; and Guillain-Barré Syndrome. The most common adverse reactions (≥10% in vaccine recipients and at least 5% greater than in placebo recipients) were runny nose or

nasal congestion, fever over 100°F (children ages 2 years through 6 years), and sore throat (adults).

Indicated Population and Use

Individuals 2 through 17 years of age should not self-administer FLUMIST. Actors in the scene at the diner appear to be 17 years of age or younger. They had ordered milkshakes and are discussing ordering FLUMIST online, and the overall impression is that these teenagers are able to purchase FLUMIST online and use it themselves in the absence of a caregiver. Indeed, one girl explains to another that "FLUMIST is a vaccine you give yourself." The waitress asks them incredulously, "You do what at home?" This is concerning because it lacks important contextual information regarding who may obtain and self-administer FLUMIST. Specifically, the presentation misleadingly suggests that a minor may order FLUMIST online and use it. The statement in small text in another scene of the video that reads, "A caregiver should administer FLUMIST to individuals 2 through 17 years of age," is not sufficient to mitigate the misleading impression created by these representations.

Presentation of Risk Information

The presentation of limitations and risk information in the TV ad is not reasonably comparable to the presentation of benefits. Specifically, the fast pacing of the risk concepts and the presentation of compelling and attention-grabbing visuals during the presentation of risk information, all of which are unrelated to the risk message, in addition to frequent scene changes, compete for the viewers' attention and make it difficult for the viewer to adequately process and comprehend the risk information. Moreover, the presentation of the major statement is not presented in a clear, conspicuous, and neutral manner. The loud background music and visual distractions, including numerous scene changes, quick camera movements, and close-ups, interfere with the viewer's ability to read the SUPERs while processing the audio information disclosing the risks associated with use of FLUMIST. In addition, the SUPERs are not easily seen on screen because the size of the text is relatively small and below the action in the frames. The overall effect undermines the communication of the risk information and the consequences that may result from the use of FLUMIST.

Conclusion and Requested Action

For the reasons described above, the TV Ad misbrands FLUMIST and makes its distribution in violation of the FD&C Act. *See* 21 U.S.C. §§ 352(n), 321(n), & 331(a); *cf.* 21 CFR § 202.1(e)(1) & (e)(5).

This letter notifies you of our concerns and provides you with an opportunity to address them. You should 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 FLUMIST that contain representations such as those

described above, and explaining your plan for discontinuation of such communications, or for ceasing distribution of FLUMIST.

If you believe that your product is 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 its implementing regulations.

Please direct your response to the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, Building 71, 5th Floor, 10903 New Hampshire Avenue, Silver Spring, MD 20993. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter and refer to the BLA/STN numbers. Submit your response to your eCTD under the heading 1.15.1.6. We remind you that only written communications are considered official responses.

Questions related to the submission of your response letter should be emailed to CBERAPLB@fda.hhs.gov.

Sincerely,

for

Vinay Prasad M.D., M.P.H.
Director
Center for Biologics Evaluation and Research