Our STN: BL 125020/2982

SUPPLEMENT APPROVAL/
COMPARABILITY PROTOCOL

MedImmune, LLC
Attention: Rushin Jhala
One MedImmune Way
Gaithersburg, MD 20878

September 20, 2024

Dear Mr. Jhala,

We have approved your request received August 21, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine Live, Intranasal (FluMist), manufactured at your Liverpool, United Kingdom and (b) (4) facilities to update labeling to include self-administration or administration by a caregiver in a non-clinical setting.

We also approve a comparability protocol to qualify alternative insulated shippers used for the shipment of FluMist for self-administration or administration by a caregiver in a non-clinical setting.

COMPARABILITY PROTOCOL

Under 21 CFR 601.12(e), approval of a comparability protocol may justify a reduced reporting category for a particular change. You should report information confirming that the change meets the requirements specified in your approved comparability protocol as a **Supplement – Changes Being Effected in 30 Days** (21 CFR 601.12(c)). You should include the information described in 21 CFR 601.12 (b)(3) in this supplement. Although you may distribute the product made using this change 30 days after FDA receives the supplement, continued use of the change will be subject to our final approval of the supplement.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling: Package Insert, Patient Package Insert, and Instructions for Use submitted under amendment 23 dated August 13, 2024, and the draft carton and container labels submitted under amendment 24, dated August 14, 2024.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert, Patient Package Insert, and Instructions for Use submitted on August 13, 2024. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 14, 2024, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125020 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your correspondence of August 16, 2024, as outlined below:

1. Real-world effectiveness of the live-attenuated influenza vaccine (LAIV) via home administration in individuals aged 2-49 years in the United States

    Final Protocol Submission: April 30, 2028

    Interim Report #1: August 31, 2029

    Interim Report #2: August 31, 2030

    Study/Trial Completion Date: April 30, 2031

    Final Report Submission: October 31, 2031

Please submit clinical protocols to your IND 13897, and a cross-reference letter to BLA STN BL125020 explaining that this protocol was submitted to the IND.

If the information in the final study report supports a change in the labeling, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment Final Study Report**

For each postmarketing study, subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN BL 125020 until all requirements and commitments subject to the reporting requirements of section 506B of

the Federal Food, Drug, and Cosmetic Act (FDCA) are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your correspondence of September 12, 2024, as outlined below:

2. To submit a Detailed Mitigation Plan to the BLA within 4 months of the approval of STN 125020/2982; to submit quarterly reports with return-shipment program compliance data for the pilot season and first three full seasons, to submit a mid-point (end of Pilot Season and Season 1) report and updated mitigation plan at the end of the first full season; and to work towards achieving 100% compliance rate for the return shipment program, with ongoing mitigation measures to improve return shipment program compliance during all seasons.

   Detailed Mitigation Plan Submission: 01/31/2025

   Mid-Point Report with Updated Mitigation Plan: 05/31/2027

   Final Report Submission: 05/31/2029

We request that you submit information concerning this chemistry, manufacturing, and control postmarketing commitment, (mitigation plans, quarterly reports, and annual reports) to your BLA STN BL 125020, as Correspondence Status Update (CSU) submissions. You may include your 4th quarter report each year as part of the annual report CSU submission. Submit your final report to your BLA, STN BL 125020 as a Final Report submission. Please refer to the sequential number for the commitment.

Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment Final Study Report**

For each postmarketing commitment not subject to the reporting requirements of 21 CFR 601.70, you may report the annual status to FDA as a **Postmarketing Study Commitment – Correspondence Status Update**. The status report for this commitment should include:

- the sequential number for each study as shown in this letter;
- the submission number associated with this letter;
- describe what has been accomplished to fulfill the non-section 506B PMC; and,
- summarize any data collected or issues with fulfilling the non-section 506B PMC.

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **Supplement contains Postmarketing Commitment Final Study Report**.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Rebecca Reindel, MD
Director
Division of Clinical & Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research