Our STN: BL 125020/2867 **SUPPLEMENT APPROVAL**

MedImmune, LLC
Attention: Asim Abdul
One MedImmune Way
Gaithersburg, MD 20878

January 12, 2023

Dear Mr. Abdul:

We have approved your request received August 19, 2022, 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 facility, to include minor, non-seasonal editorial changes to the package insert and carton and container labels intended for implementation during the 2023-2024 flu season.

LABELING

We hereby approve the draft content of labeling: draft container labels submitted on August 19, 2022.

CONTENT OF LABELING

CARTON AND CONTAINER LABELS

Please electronically submit final printed container labels identical to the container labels submitted on August 19, 2022 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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

Sincerely,

For Rebecca Reindel, MD
Deputy Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research