U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 103914/7017

SUPPLEMENT APPROVAL
February 20, 2026

Sanofi Pasteur Inc.
Attention: Michael F. Stirr
Discovery Drive
Swiftwater, PA 18370

Dear Mr. Stirr:

We have approved your request received October 22, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine (Fluzone), to include the 2026 Southern Hemisphere formulations and associated labeling revisions for Fluzone and Fluzone High-Dose formulations, manufactured at Sanofi Pasteur Inc. (Swiftwater, PA), (b) (4) [redacted] facilities.

LABELING

We hereby approve the draft content of labeling:

- Package Insert for Fluzone Southern Hemisphere and Fluzone High-Dose Southern Hemisphere, submitted under amendment # 4, dated February 12, 2026;
- Draft carton submitted under amendment # 3, dated February 9, 2026, for Fluzone Southern Hemisphere 10 single-dose prefilled syringes, Fluzone Southern Hemisphere -5ml multi-dose vial, and Fluzone High-Dose Southern Hemisphere 10 single dose prefilled syringes;
- Draft container labels submitted on October 22, 2025, for Fluzone High-Dose Southern Hemisphere 0.5 ml prefilled syringes; on November 26, 2025, for Fluzone Southern Hemisphere 0.5 ml prefilled syringes and Fluzone Southern Hemisphere 0.5 ml multi-dose vial, under amendment # 1.

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 https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources. Content of labeling must be identical to the Package Insert submitted on February 12, 2026. 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 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/spl-standard-content-labeling-technical-qs.

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 October 22, 2025, November 26, 2025, and February 9, 2026, 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 103914 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.

SAFETY LABELING CHANGES 505(o)(4) – CHANGES BEING EFFECTED

Please refer to the January 9, 2026, Notification for Safety Labeling Change to STN BL103914/7093. As soon as possible, but no later than March 6, 2026, please submit a Changes Being Effected (CBE-0) supplement with changes to the approved labeling that includes only language identical to that specified in the January 9, 2026, Safety Labeling Change Notification letter.

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

Sincerely,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research