



Our STN: BL 103914/7104

**SUPPLEMENT APPROVAL**

July 1, 2026

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

Dear Mr. Stirr:

We have approved your request received March 18, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine (Fluzone), for Fluzone and Fluzone High-Dose formulations manufactured at Sanofi Vaccines US Inc. (Swiftwater, PA), (b) (4) facilities, to include the 2026-2027 United States formulation and associated labeling revisions.

## **LABELING**

We hereby approve the draft content of labeling: Package Inserts submitted under amendment #6, dated June 30, 2026; and draft container labels for Fluzone and Fluzone High-Dose (0.5 mL Single-Dose), submitted on March 18, 2026, and draft carton and container labels submitted under amendment #3, dated May 20, 2026.

We acknowledge your commitment to implement the labeling changes approved under this supplement for Fluzone and Fluzone High-Dose, at the next printing. We recognize that immediate reprinting of labels to incorporate the FDA-requested revisions would significantly impact the timely availability of vaccine supply for the 2026–2027 season. We also acknowledge your commitment to submit the final labels incorporating FDA-approved revisions under STN 103914/7104 in Structured Product Labeling (SPL) format no later than 14 days from the date of this letter.

## **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, submitted on June 30, 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 <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 draft container labels for Fluzone and Fluzone High-Dose (0.5 mL Single-Dose), submitted on March 18, 2026, and draft carton and container labels submitted under amendment 3, dated May 20, 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.

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