Our STN: BL 103914/6951

SUPPLEMENT APPROVAL
April 29, 2025

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

Dear Mr. Stirr:

We have approved your request received November 27, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine (Fluzone), to update the USPI and associated labeling (*i.e.,* blister pack lidding) for Fluzone High Dose, manufactured at Swiftwater, PA, to clarify the dose and two type of packaging of 10 prefilled syringes (2 rows of 5 single-dose prefilled syringes, or 5 sleeves, with each sleeve containing 2 single-dose prefilled syringes), of Fluzone High-Dose, to prevent medication errors.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 2, dated March 31, 2025, and the blister pack lidding labels submitted under amendment 1, dated March 21, 2025.

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 March 31, 2025. 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 blister pack lidding labels identical to the blister pack lidding labels submitted on March 21, 2025, 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)).

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

Sincerely,

R. Douglas Pratt, MD, MPH
Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research