Our STN: BL 103914/7115

SUPPLEMENT APPROVAL
March 23, 2026

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

Dear Mr. Stirr:

We have approved your request received March 5, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine (FLUZONE), to include new safety information (NSI) regarding an increased risk of febrile seizures in children 6 months through 4 years of age, following vaccination with any influenza vaccine, in "Highlights of Prescribing Information", "Warnings and Precautions", "Adverse Reactions", and "References" sections of the Package Insert for FLUZONE Southern Hemisphere in accordance with section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA).

The review of this supplement was associated with our January 9, 2026, SAFETY LABELING CHANGE NOTIFICATION LETTER, notifying you, under Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA), of new safety information that we believe should be included in the labeling for FLUZONE. This information pertains to an increased risk of febrile seizures following vaccination with any influenza vaccine in children 6 months through 4 years of age, observed in two postmarketing observational studies conducted in the Biologics Effectiveness and Safety System (BEST).

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment #1, dated March 9, 2026.

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 9, 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.

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,

David C. Kaslow, MD
Acting Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research