Our STN: BL 125285/613

SUPPLEMENT APPROVAL
PMR FULFILLED
March 31, 2025

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

Dear Mr. Stirr:

We have approved your request received May 31, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine (Flublok) manufactured at (b) (4) facility and at (b) (4) to revise the indication to include use of Flublok in persons 9 through 17 years of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT05513053, NCT05513391.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 20, dated March 26, 2025, and the draft carton label submitted under amendment 18, dated March 18, 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 26, 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 the final printed carton label identical to the carton label submitted on March 18, 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 125285 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.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirements #1 and #2 identified in the April 18, 2022, Release PREA PMR/New PREA PMR letter for BLA STN BL 125285/471 for Influenza Vaccine (Flublok). The requirements addressed in this submission are as follows:

1. Deferred pediatric study under PREA to evaluate the safety and immunogenicity of Flublok Quadrivalent in children ages 3 through 8 years (VAP00026).

2. Deferred pediatric study under PREA to evaluate the safety and immunogenicity of Flublok Quadrivalent in children and adolescents ages 9 through 17 years of age and adults ages 18 through 49 years (VAP00027).

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

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