

## **SUPPLEMENT APPROVAL**

Our STN: BL 103914/6208

Sanofi Pasteur Inc.  
Attention: Michael F. Stirr  
Discovery Drive  
Swiftwater, PA 18370-0187

January 23, 2019

Dear Mr. Stirr:

We have approved your request dated March 30, 2018, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Influenza Vaccine (Fluzone®) manufactured at your Swiftwater, PA (b) (4) facilities to include the use of a 0.5 mL single dose presentation of Fluzone Quadrivalent formulation in children 6 to <36 months of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 02915302.

### **LABELING**

We hereby approve the draft package insert and draft carton labeling submitted under amendment 8, dated January 11, 2019.

### **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>. 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.

### **PACKAGE AND CONTAINER LABELS**

Please electronically submit final printed package labels that are identical to the package labels submitted on January 11, 2019, according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD*

*Specifications* at <https://www.fda.gov/downloads/drugs/guidancecompliance/regulatoryinformation/guidances/ucm333969.pdf>.

All final labeling should be submitted as Product Correspondence to this BLA STN 103914/6208 at the time of use (prior to marketing) 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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

Sincerely,

Doran L. Fink, M.D., Ph.D.  
Deputy Director - Clinical  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research