SUPPLEMENT APPROVAL

Our STN: BL 103914/6249

Sanofi Pasteur Inc.
Attention: Michael F. Stirr
Discovery Drive
Swiftwater, PA 19370

February 4, 2019

Dear Mr. Stirr:

We have approved your request submitted October 11, 2018, received October 12, 2018, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Influenza Vaccine (Fluzone®), manufactured at your Swiftwater, PA and (b) (4) facilities, to include the 2019 Southern Hemisphere Fluzone Quadrivalent formulation and associated labeling revisions.

LABELING
We hereby approve the draft package insert and carton labeling submitted under amendment 1, dated November 16, 2018, and the draft container labeling submitted on October 11, 2018.

Please provide your final content of labeling, including the carton and container labels, in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in 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 titled, "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 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 advertisement 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 include these changes.

We will include information contained in the above-referenced supplement in your Biologics License Application file.

Sincerely,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research