DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

SUPPLEMENT APPROVAL

Our STN: BL **103930/5203**

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

August 6, 2015

Dear Mr. Stirr:

We have approved your request to supplement your biologics license application for Poliovirus Vaccine Inactivated (IPOL®) manufactured at your Marcy L'Etoile, France facility, to include revisions to your package insert (PI) and other labeling items. Changes being approved under this supplement include the following:

- Change "The residual calf serum protein is less than 1 ppm in the final vaccine." to "The residual calf bovine serum albumin is less than 50 ng/dose in the final vaccine" under section titled "DESCRIPTION" in the package insert (PI)
- Update the latex-free statement for compliance to the FDA's March 2013 Draft Guidance concerning latex under section titled "DESCRIPTION" in the PI
- Remove "Category C" text under section titled "PREGNANCY" in the PI
- Remove references to syringe presentation in the PI as it has been discontinued
- Change site of manufacture from "Lyon" to "Marcy L 'Etoile" in last page under "Manufactured by" in the PI, and in the carton and container labels
- Implement additional minor editorial changes in the PI, and in the carton and container labels

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. 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 [OPTION: and FDA Form 2567 as appropriate].

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 includes thischange.

We will include the information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccine and
Related Product Application
Office of Vaccines and
Research and Review
Center for Biologics
Evaluation and Research

Attachment: Approved Final Draft Labeling