

Our STN: BL 125145/532

SUPPLEMENT APPROVAL

Sanofi Pasteur Limited
Attention: Michael F. Stirr
1755 Steele Avenue West
Toronto, Canada

December 19, 2019

Dear Mr. Stirr:

We have approved your request submitted and received June 20, 2019, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine (Pentacel[®]) manufactured at your Toronto, Canada facility to include a change from MRC-5-derived to Vero cell-derived Inactivated Poliovirus Vaccine (IPV), and to update the package insert and carton and container labels to be distributed with the Vero cell-derived IPV Pentacel[®] formulation.

Under this approval, your annual stability studies for reconstituted final drug product will include tests for ^{(b) (4)} physical appearance, ^{(b) (4)} polyribosylribitol phosphate content.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 16, dated December 16, 2019, the draft carton and ActHIB container labeling submitted under amendment 13, dated October 16, 2019 and the container labeling submitted under amendment 1, dated August 21, 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 and container labels that are identical to the package and container labels submitted on August 21, 2019 and October 16,

2019, 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 125525/123 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,

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