DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

SUPPLEMENT APPROVAL

Our STN: BL **103935/5360**

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

December 16, 2015

Dear Mr. Stirr:

We have approved your request to supplement your biologics license application for Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), Act-HIB®, to update the package insert (PI) and convert it to the Physician Labeling Rule (PLR) format, include revisions to section 6 (Adverse Reactions) of the PI, and revise the carton and diluent container labeling for consistency with the revised PI.

Under this approval, you removed from the PI references to TriHIBit® [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed (DTaP)] and Tripedia® [Diphtheria and Tetanus DTaP Toxoids and Acellular Pertussis Vaccine Adsorbed] as well as references to studies conducted using oral polio vaccine and whole cell diphtheria, tetanus and pertussis vaccines, as these products are no longer approved for use or marketed in the US.

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.

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 these changes.

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

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Attachment: Approved Final Draft Labeling