**SUPPLEMENT APPROVAL**

OUR STN: BL 125111/646

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

September 29, 2017

Dear Mr. Stirr:

We have approved your request dated June 1, 2017, to supplement your biologics license application submitted under section 351(a) of the Public Health Service Act (42U.S.C. 262) for Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Adacel®) at your Swiftwater, PA facility for a change to a pre-filled syringe tip cap that is not made with natural rubber latex.

We hereby approve the draft labeling submitted to us on September 29, 2017.

Please submit your final draft labeling and carton and container labels as an amendment to this supplement under STN 125111/646 by October 13, 2017.

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 BLA 125111 at the time of use (prior to marketing) and include implementation information on Form FDA 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 *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 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 biologics license application file.

Sincerely yours,

Jay E. Slater, M.D.
Director
Division of Bacterial, Parasitic
and Allergenic Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research