Our STN: BL125111/1145

SUPPLEMENT APPROVAL
July 30, 2026

Sanofi Vaccines Canada Ltd.
Attention: Michael Stirr
1755 Steeles Avenue West
Toronto, Ontario
Canada M2R 3T4

Dear Mr Stirr:

We have approved your request received May 30, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (ADACEL) to include the following changes at your facility in Toronto, Ontario, Canada:

- Replacement of the Filamentous Haemagglutinin (FHA) Mouse Immunogenicity Assay with the FHA Antigenicity Enzyme-Linked Immunosorbent Assay (ELISA)

- Replacement of the Fimbriae Types 2 and 3 (FIM) Mouse Immunogenicity Assay with the FIM Antigenicity ELISA

- Replacement of the Pertactin (PRN) Mouse Immunogenicity Assay with the PRN Antigenicity ELISA.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 4, dated July 24, 2026.

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. Content of labeling must be identical to the Package Insert, submitted on July 24, 2026. 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.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Sharon Tennant, PhD, MPH
Acting Director
Division of Bacterial, Parasitic, and Allergenic Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research