Our STN: BL103171/5374

SUPPLEMENT APPROVAL/
COMPARABILITY PROTOCOL
August 26, 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 February 24, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for, Tetanus and Diphtheria Toxoids Adsorbed (TENIVAC) to include the following changes at your facility in Toronto, Ontario, Canada:

- Replacement of the Diphtheria Potency (b) (4) Method with the Diphtheria Toxoid Antigenicity Enzyme-Linked Immunosorbent Assay.

- Replacement of the Tetanus Potency (b) (4) Method with the Tetanus Toxoid Antigenicity Enzyme-Linked Immunosorbent Assay.

- A Comparability Protocol for the qualification of the anti-diphtheria antibody conjugates to be used as critical reagents for release and stability testing of DAPTACEL by the In Vitro Diphtheria Antigenicity Assay.

- A Comparability Protocol for the qualification of the anti-tetanus antibody conjugates to be used as critical reagents for release and stability testing of DAPTACEL by the In Vitro Tetanus Antigenicity Assay.

COMPARABILITY PROTOCOL

Under 21 CFR 601.12(e), approval of a comparability protocol may justify a reduced reporting category for a particular change. You should report information confirming that the change meets the requirements specified in your approved comparability protocol as a **Supplement - Changes Being Effected** (21 CFR 601.12(c)(5)). You should include the information described in 21 CFR 601.12 (b)(3) in this supplement. Although you may distribute the product made using this change immediately after FDA receives the supplement, continued use of the change will be subject to our final approval of the supplement.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 7, dated August 25, 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 August 13, 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