Our STN: BL 103171/5285 **SUPPLEMENT APPROVAL**

Sanofi Pasteur Limited
Attention: Michael F. Stirr
1755 Steeles Avenue West
Toronto, Ontario
Canada M2R 3T4

December 16, 2022

Dear Mr. Stirr:

We have approved your request received December 16, 2022, 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), manufactured at your Toronto, Canada facility for the following:

1. To include the language, "Syncope (fainting) has been reported following vaccination with TENIVAC. Procedures should be in place to avoid injury from fainting (5.8)" under *Warnings and Precautions* in the Highlights of Prescribing Information of the United States Package Insert (USPI).

2. To include the language, "Syncope (fainting) has been reported following vaccination with TENIVAC. Procedures should be in place to avoid injury from fainting," in Section 5, *Warnings and Precautions*, Subsection 5.8, *Syncope* of the Full Prescribing Content of the USPI.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under Amendment 1 dated December 16, 2022.

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, (enlist) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on June 3, 2022. 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.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 103171 at the time of use 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,

Rebecca Reindel, M.D.
Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research