Our STN: BL 125701/262

**SUPPLEMENT APPROVAL**
**PMRs FULFILLED**
May 23, 2025

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

Dear Mr. Stirr:

We have approved your request received July 23, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Meningococcal (Groups A, C, Y, W) Conjugate Vaccine (MenQuadfi) manufactured at your Swiftwater, Pennsylvania facility to update the Package Insert to include safety and effectiveness data from postmarketing requirement (PMR) studies MET41, MET42 and MET61 that support lowering the age for use to include individuals 6 weeks through 23 months of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT03673462, NCT03537508, NCT03691610 and NCT01049035.

## LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 43, dated May 23, 2025, and the draft carton labels submitted under amendments 33 and 40, dated May 6, 2025, and May 20, 2025, respectively.

## 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 May 23, 2025. 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.

## CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on May 6, 2025 and May 20, 2025, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125701 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

## ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80). You must submit distribution reports as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-

submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

**FULFILLED POSTMARKETING REQUIREMENTS**

This submission fulfills your postmarketing requirements (PMRs) 1, 2 and 3 identified in the April 23, 2020, approval letter for BLA STN BL 125701/0 for Meningococcal (Groups A, C, Y, W) Conjugate Vaccine. The requirements addressed in this submission are as follows:

1. Deferred pediatric study (MET41) under PREA to evaluate the safety of MenQuadfi in infants and toddlers 6 weeks through 12 months of age.

2. Deferred pediatric study (MET42) under PREA to evaluate the immunogenicity and safety of MenQuadfi in infants and toddlers 6 weeks through 18 months of age.

3. Deferred pediatric study (MET61) under PREA to evaluate the immunogenicity and safety of MenQuadfi in infants and toddlers 6 weeks through 23 months of age.

**PEDIATRIC REQUIREMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

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

Sincerely,

R. Douglas Pratt, MD, MPH
Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research