Our STN: BL 125814/428

SUPPLEMENT APPROVAL
PMR FULFILLED
June 17, 2026

Merck Sharp & Dohme LLC
Attention: Neika Vendetti
P.O. Box 1000
North Wales, PA 19454-2505

Dear Ms. Vendetti:

We have approved your request received on August 18, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Pneumococcal 21-valent Conjugate Vaccine (CAPVAXIVE) to extend the indication for CAPVAXIVE to include children and adolescents 2 through 17 years of age with increased risk of pneumococcal disease.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT06177912.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling: Package Insert, Patient Package Insert, and the Carton labels submitted under amendment 14, on June 11, 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 and Patient Package Insert, submitted on June 11, 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 A's* 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 labels identical to the Carton labels submitted on June 11, 2026, 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 125814 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.

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfills your postmarketing requirement PMR #2 identified in the June 17, 2024, approval letter for BLA STN BL 125814/0 for Pneumococcal 21-valent Conjugate Vaccine (CAPVAXIVE). The requirement addressed in this submission is as follows:

PMR #2. Deferred pediatric study under PREA to evaluate the safety and immunogenicity of CAPVAXIVE in pediatric patients ages 2 to <18 years.

We remind you that there is a PMR still open. For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of the BLA until all Requirements and Commitments subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act are fulfilled or released. The status report for each study should include:

- the sequential number for each study;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments.

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 files.

Sincerely,

Andrea Hulse, MD
Acting Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research