Our STN: BL 125741/6

SUPPLEMENT APPROVAL
PMR FULFILLED

Merck Sharp and Dohme Corp.
Attention: Jumi Yi, M.D.
351 N. Sumneytown Pike
North Wales, PA

June 17, 2022

Dear Dr. Yi:

We have approved your request received September 30, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Pneumococcal 15-valent Conjugate Vaccine (VAXNEUVANCE), manufactured in (b) (4) to include results from 7 clinical studies (V114-008, V114-023, V114-024, V114-027, V114-029, V114-030, and V114-031) conducted in children 6 weeks through 17 years of age and to fulfill PREA PMRs #1, #2, #3, #4.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT02987972, NCT03731182, NCT03885934, NCT03620162, NCT03893448, NCT03921424 and NCT03692871.

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, including the Package Insert submitted under amendment 30, dated June 17, 2022, Patient Package Insert submitted under amendment 23, dated June 1, 2022, and the draft carton and container labels submitted under amendment 28, dated June 14, 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, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert, Patient Package Insert, Instructions for Use, and Medication Guide] submitted on June 17, 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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 June 14, 2022, 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 125741 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.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirements identified in the July 16, 2021, approval letter for BLA STN BL 125741/0 for VAXNEUVANCE. The requirements addressed in this submission are as follows:

1. Deferred pediatric study under PREA (Study V114-029) to evaluate the safety and immunogenicity of VAXNEUVANCE in healthy infants 6 through 12 weeks of age as a 4-dose schedule (2, 4, 6, and 12 to15 months of age).

   Final Protocol Submission: February 22, 2019

   Study Completion Date: December 31, 2021

   Final Report Submission: April 30, 2022

2. Deferred pediatric study under PREA (Study V114-024) to evaluate the safety and immunogenicity of VAXNEUVANCE when given as catch-up vaccination in healthy children 7 months through 17 years of age.

   Final Protocol Submission: December 5, 2019

   Study Completion Date: September 30, 2021

   Final Report Submission: December 31, 2021

3. Deferred pediatric study under PREA (Study V114-027) to evaluate the safety and immunogenicity of four-dose schedules of VAXNEUVANCE and Prevnar 13 with doses administered at 2, 4, 6 and 12 to 15 months of age, as compared to mixed schedules which begin with Prevnar 13 and change to VAXNEUVANCE at doses 2, 3 or 4.

   Final Protocol Submission: August 16, 2018

   Study Completion Date: April 30, 2021

   Final Report Submission: July 31, 2021

4. Deferred pediatric study under PREA (Study V114-030) to evaluate the safety and immunogenicity of VAXNEUVANCE in HIV-infected children 6 through 17 years of age.

   Final Protocol Submission: December 5, 2019

   Study Completion Date: August 31, 2022

   Final Report Submission: December 31, 2022

This completes all of your PMRs and PMCs. As such, your **Annual Status Report of Postmarketing Requirements/Commitments** is no longer required until such time a new Requirement or Commitment subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act is issued.

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,

Doran L. Fink, M.D.
Deputy Director – Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research