Our STN: BL125731/189 **SUPPLEMENT APPROVAL**

Wyeth Pharmaceuticals, LLC
Attention: Sharon Bauer
235 East 42 Street
New York, NY 10017

April 27, 2023

Dear Ms. Bauer:

We have approved your request received October 26, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for 20-valent Pneumococcal Conjugate Vaccine (PREVNAR 20) to include an extended indication for active immunization in individuals 6 weeks of age and older, for the active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F and in individuals 6 weeks through 5 years of age, for the active immunization for the prevention of otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT03512288; NCT04382326; NCT04379713; and NCT04642079.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 35, dated April 18, 2023, and the draft carton and container labels submitted under amendment 0 dated October 26, 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 submitted on April 18, 2023. 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 October 26, 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 125731, 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 this change.

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfills your postmarketing requirements PMR #s 2, 3 and 4 identified in the June 10, 2021, approval letter for BLA STN BL 125731/0 for Pneumococcal 20-valent Conjugate Vaccine. The requirements addressed in this submission are as follows:

2. Deferred pediatric study (B7471011) under PREA to evaluate the safety and immunogenicity of the 2, 4, 6, and 12-month schedule of Prevnar 20 in infants and toddlers 6 weeks through 12 months of age in the United States (U.S.).

   Final Protocol Submission: May 8, 2020

   Study Completion Date: August 31, 2022

   Final Report Submission: December 31, 2022

3. Deferred pediatric study (B7471013) under PREA to evaluate the safety of the 2, 4, 6, and 12-month schedule of Prevnar 20 in infants and toddlers 6 weeks through 12 months of age in the U.S., Canada and Europe.

   Final Protocol Submission: March 23, 2020

   Study Completion Date: August 31, 2022

   Final Report Submission: December 31, 2022

4. Deferred pediatric study (B7471014) under PREA to evaluate the safety and immunogenicity of Prevnar 20 in children and adolescents 15 months through 17 years of age in the U.S.

   Final Protocol Submission: September 11, 2020

   Study Completion Date: December 31, 2022

   Final Report Submission: December 31, 2022

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 the invasive pneumococcal disease indication and the otitis media indication for all relevant pediatric age groups for this application.

We are waiving the pediatric study requirement for the otitis media indication for individuals 0 to <6 weeks of age, because the drug or biological product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in a substantial number of pediatric patients.

We are waiving the pediatric study requirement for the otitis media indication for individuals 6 years through 17 years of age, because the necessary studies are impossible or highly impracticable due to the low incidence of acute otitis media in this age group.

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

Sincerely,

For Joseph G. Toerner, MD, MPH
Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research