DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

**SUPPLEMENT APPROVAL**

Our STN: BL **125324/1196**

Wyeth Pharmaceuticals, Inc.
Attention: Elysia Tusavitz
401 N. Middletown Road
Pearl River, NY 10965

Dear Ms. Tusavitz:

We have approved your request to supplement your biologics license application for Pneumococcal 13-valent Conjugate Vaccine (Diphtheria $CRM_{197}$ Protein), Prevnar 13, to update the package insert to include data from the CAPiTA confirmatory efficacy study in adults**.**

We licensed Prevnar 13 on December 30, 2011, under the accelerated approval regulations with a post-marketing requirement (21 CFR 601.41). As stated in our May 19, 2015, letter to you, approval of the previously submitted supplement 125324/1194 fulfilled your requirement to submit the results of the CAPiTA confirmatory efficacy study to your Biologics License Application.

The review of this product was associated with the following National Clinical Trial (NCT) number: NCT00744263.

Under 21 CFR 201.57(c)(18), patient labeling must be reprinted at the end of the package insert. We request that the text of information distributed to patients be printed in a minimum of 10-point font.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h [OPTION: and FDA Form 2567 as appropriate].

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled, “SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 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 advertisement 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/these] change(s).

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Attachment: Approved Final Draft Labeling