SUPPLEMENT APPROVAL

OUR STN: BL **125324/1561**

Wyeth Pharmaceuticals
Attention: Patrick Thomas
401 N. Middletown Road
Pearl River, NY 10965

March 24, 2017

Dear Mr. Thomas:

We have approved your May 26, 2016,request to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Prevnar 13® to update the United States Prescribing Information (USPI) to include results from the study B1851138 *"A Phase 4, Randomized, Double-Blind Trial to Evaluate the Immunogenicity and Safety of a 13-valent Pneumococcal Conjugate Vaccine When Administered Concomitantly With Seasonal Inactivated Influenza Vaccine in Adults 50 Years and Older Who Received 1 or More Doses of 23-valent Pneumococcal Polysaccharide Vaccine Prior to Study Enrollment"*.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT02124161

We hereby approve the draft package insert labeling submitted in your communication of March 24 2017.

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 BLA 125324 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

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 *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 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)).

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

Sincerely yours,

Wellington Sun
Director
Division of Vaccines and
Related Product Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research