SUPPLEMENT APPROVAL
PMR FULFILLED

Our STN: BL 125347/309

GlaxoSmithKline Biologicals
Attention: Michael P. Schwartz, Ph.D.
14200 Shady Grove Road
VR1500
Rockville, Maryland 20850-7464

April 30, 2018

Dear Dr. Schwartz:

We have approved your request dated June 30, 2017, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Haemophilus B Conjugate Vaccine (Tetanus Toxoid Conjugate), Hiberix®, manufactured in (b) (4) Belgium, to include safety and effectiveness data from the booster phase of Study Hib-097 that verify and describe the clinical benefit of Hiberix administered as a booster dose for active immunization for the prevention of invasive disease caused by *Haemophilus influenzae* type b.

We approved BLA STN 125347/0 on August 19, 2009, under 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses. Approval of this supplement (STN 125347/309) fulfills the following postmarketing requirement for an adequate and well-controlled study to verify and describe the clinical benefit of the booster phase of Hiberix made under 21 CFR 601.41.

FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES

1. To conduct Study Hib-097, a comparative safety and immunogenicity clinical trial of primary and booster immunization with Hiberix relative to U.S. licensed control vaccines.

   Final Protocol Submission: Third Quarter of 2009

   Study/Trial Completion: First Quarter of 2010

   Final Report Submission: Fourth Quarter of 2013

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 01000974.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 5, dated April 17, 2018.

Please provide your final content of labeling including the carton and container labels in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to BLA STN 125347 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)).

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.

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