SUPPLEMENT APPROVAL
PMR FULFILLED

Our STN: BL 125127/834

GlaxoSmithKline Biologicals
Attention: Dr. Weila Wang
14200 Shady Grove Road
VR1500
Rockville MD 20850-7464

January 11, 2018

Dear Dr. Wang:

We have approved your request dated March 15, 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 Influenza Vaccine (Fluarix® Quadrivalent) manufactured at Dresden, Germany, facility to extend the age range for use of Fluarix Quadrivalent to include children 6 to 35 months of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT01439360, NCT01702454, NCT02207413.

LABELING
We hereby approve the draft package insert labeling submitted under amendment 10, dated January 10, 2018, and the draft carton label submitted under amendment 5, dated September 12, 2017.

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 125127 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.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS
This submission fulfills your postmarketing requirement#1 identified in the December 14, 2012 approval letter for BLA STN 125127/513 for Influenza Vaccine. The requirement addressed in this submission is as follows:

1. Deferred pediatric study under PREA for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in Fluarix Quadrivalent, in pediatric patients ages 6 months to 35 months of age.

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 yours,

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