Our STN: BL 125265/585 **SUPPLEMENT APPROVAL**

GlaxoSmithKline Biologicals
Attention: Angela Natilla, Ph.D. November 12, 2019
14200 Shady Grove Road
VR1500
Rockville, MD 20850-7464

Dear Dr. Natilla:

We have approved your request submitted and received on June 4, 2019, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Rotavirus Vaccine, Live, Oral (ROTARIX), manufactured at your [redacted] Belgium locations, to update the product labeling to include revisions to Section 8 of the package insert to comply with 21 CFR 201.57(c)(9)(i) - (iii) to address the Pregnancy, Lactation and Labeling Rule and minor updates to the Highlights and Sections 1, 6, 14, 17, and the accompanying patient labeling. Under this approval, Sections 8.1 and 8.2 are removed from the package insert as they are not applicable to the age group approved for use.

**LABELING**

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft package insert labeling and accompanying patient labeling submitted under Amendment 1, dated October 31, 2019.

**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. 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.

All final labeling should be submitted as Product Correspondence to this BLA STN 125265 at the time of use (prior to marketing) 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 these changes.

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

Sincerely,

Doran L. Fink, M.D., Ph.D.
Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research