Our STN: BL 125265/834

SUPPLEMENT APPROVAL
September 25, 2026

GlaxoSmithKline Biologicals
Attention: Yenny Ramos
2000 Tower Oaks Blvd.
Suite 360
Rockville, MD 28502

Dear Ms. Ramos:

We have approved your request received May 8, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Rotavirus Vaccine, Live, Oral (ROTARIX) to update Section 6.2 Postmarketing Experience in the Package Insert to include the following language under Gastrointestinal Disorders subsection: "Gastroenteritis associated with prolonged vaccine viral shedding in infants with Severe Combined Immunodeficiency Disease (SCID) resulting in severe diarrhea *[see Contraindications (4.4)]*. Acute gastroenteritis associated with vaccine viral shedding in infants without known immune deficiency."

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 4, dated August 28, 2026.

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. Content of labeling must be identical to the Package Insert submitted on August 28, 2026. 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 BL 125265, at the time of use 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

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

Sincerely,

Andrea Hulse, M.D.
Acting Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research