Our STN: BL 125748/137

SUPPLEMENT APPROVAL
March 27, 2026

GlaxoSmithKline Biologicals
Attention: Lori Gibbons
1250 South Collegeville Road
Collegeville, PA 19426

Dear Ms. Gibbons:

We have approved your request received November 26, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Measles, Mumps and Rubella Vaccine Live (PRIORIX) to include the following changes:

- Replacement of the 1.25 mL Luer Lock syringe type with small round flange (supplied by (b) (4)) with a new 1.25 mL Luer Lock syringe type with large cut flange and (b) (4) rubber tip cap (supplied by (b) (4)) as the final container for the Sterile Water Diluent Component of PRIORIX manufactured at the (b) (4) facility, along with associated labeling changes to the Package Insert and the carton label.

- Update of the release specifications for the Sterile Water Diluent Component of PRIORIX, to include the replacement of the (b) (4) test with the (b) (4) test, to ensure full alignment with the current (b) (4) (b) (4) for Sterile Water For Injection.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 5, dated March 23, 2026, and the draft carton label submitted under amendment 3, dated March 4, 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 March 23, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton label identical to the carton label submitted on March 4, 2026, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125748, 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,

Jerry Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research