Our STN: BL 125122/1874

SUPPLEMENT APPROVAL
March 13, 2026

Merck Sharp & Dohme LLC
Attention: Francheska Colon-Gonzalez, Ph.D.
351 N. Sumneytown Pike
P.O. Box 1000
North Wales, PA 19454-2505

Dear Dr. Colon-Gonzalez:

We have approved your request received September 11, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Rotavirus Vaccine, Live, Oral, Pentavalent (RotaTeq) to include revisions to the Package Insert as follows:

- Section 6.2 Postmarketing Experience, under *Gastrointestinal disorders*, to include:
  "Gastroenteritis associated with prolonged vaccine viral shedding in infants with Severe Combined Immunodeficiency Disease (SCID) resulting in severe diarrhea *[see Contraindications (4.2)]*.
  Acute gastroenteritis associated with vaccine viral shedding in infants without known immune deficiency."

- Section 4.1 Hypersensitivity, revised to:
  "RotaTeq is contraindicated in infants with a demonstrated history of hypersensitivity to any component of the vaccine. Infants who develop symptoms suggestive of hypersensitivity after receiving a dose of RotaTeq should not receive further doses of RotaTeq."

- Section 4.2 Severe Combined Immunodeficiency Disease, revised to:
  "RotaTeq is contraindicated in infants with Severe Combined Immunodeficiency Disease (SCID) and should not receive RotaTeq. Postmarketing reports of gastroenteritis, including severe diarrhea and prolonged shedding of vaccine virus, have been reported in infants who were administered RotaTeq and later identified as having SCID."

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 11, dated March 12, 2026, and the draft carton labels submitted under amendment 10, dated March 11, 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 https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources. Content of labeling must be identical to the Package Insert submitted on March 12, 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 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/spl-standard-content-labeling-technical-qs.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton labels identical to the carton labels submitted on March 11, 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 125122, 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, MD, for
Acting Division Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research