SUPPLEMENT APPROVAL

Our STN: BL 125108/1328

Merck Sharp & Dohme LLC
Attention: Louise Parks Saldutti, Ph.D.
351 N. Sumneytown Pike
P.O. Box 1000
UG2D-68
North Wales, PA 19454

November 5, 2024

Dear Dr. Saldutti:

We have approved your request received May 6, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Measles, Mumps, Rubella and Varicella Virus Vaccine Live (ProQuad), manufactured at your West Point, Pennsylvania location, to revise the Package Insert to include information on a case of Congenital Rubella Syndrome following inadvertent vaccination of a pregnant woman with a measles, mumps, and rubella virus containing vaccine from an unknown manufacturer.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 3, dated October 29, 2024.

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 October 29, 2024. 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 125108, 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 change approved today.

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

Sincerely,

Rebecca Reindel, MD
Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research