Our STN: BL 125508/1434

SUPPLEMENT APPROVAL
PMC FULFILLED

Merck Sharp & Dohme LLC
Attention: Amir Khan, Ph.D.
126 East Lincoln Ave.
P.O. Box 2000
Rahway, NJ 07065

April 28, 2023

Dear Dr. Khan:

We have approved your request received June 28, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Human Papillomavirus 9-valent Vaccine, Recombinant (GARDASIL9), manufactured at your (b) (4) facilities and at (b) (4) to include clinical data from the long-term follow-up study V503-002-20 in support of modifications to the package insert.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT00943722.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 9, dated April 21, 2023, and the draft carton labels submitted under amendment 10, dated April 24, 2023.

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 April 21, 2023. 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 labels identical to the carton labels submitted on April 24, 2023, 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 125508 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)).

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.

FULFILLED POSTMARKETING COMMITMENT

This submission fulfills your postmarketing commitment #1 identified in the December 10, 2014, approval letter for BLA STN BL 125508/0 for Human Papillomavirus 9-valent Vaccine, Recombinant. The requirement addressed in this submission is as follows:

1. To complete the ongoing 10-year study extension of Protocol V503-002 to evaluate the long-term safety, immunogenicity and effectiveness of Gardasil 9 in males and females who were between 9 and 15 years of age at enrollment.

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

Sincerely,

Joseph G. Toerner, MD, MPH
Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research