SUPPLEMENT APPROVAL

Our STN: BL 125123/2209

Merck Sharp & Dohme Corp.
Attention: Long Wang, M.D., Ph.D.
351 N. Sumneytown Pike
P. O. Box 1000
UG2D68
North Wales, PA 19454

February 21, 2019

Dear Dr. Wang:

We have approved your request submitted August 30, 2018, received August 30, 2018, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Zoster Vaccine Live (Zostavax®), manufactured at the (b) (4) facility, to revise Section 6.3 Postmarketing Experience of the package insert labeling to include nervous system disorders: Guillain-Barré syndrome and facial paralysis and to revise the patient package insert (PPI) labeling to include Guillain-Barré syndrome and facial paralysis as additional side effects that have been reported with ZOSTAVAX.

LABELING

We hereby approve the draft package insert labeling for the Refrigerator Stable formulation submitted August 30, 2018, and the draft package insert labeling for the Frozen formulation submitted under amendment 2, dated February 11, 2019. Also, we hereby approve the PPI labeling for both Refrigerator Stable and Frozen formulations submitted August 30, 2018.

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

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. 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 125123, at the time of use (prior to marketing) 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.

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

Sincerely,

Doran L. Fink, M.D., Ph.D.
Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research