SUPPLEMENT APPROVAL

Our STN: BL 125123/2102

Merck Sharp & Dohme Corp.
Attention: Long Wang, M.D., Ph.D.
351 N. Summneytown Pike
P.O. Box 1000
UG2CD-48
North Wales, PA 19454

March 21, 2018

Dear Dr. Wang:

We have approved your request dated September 19, 2017, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Zoster Vaccine Live (Zostavax®), manufactured at the (b) (4) facility, to revise the package insert labeling to include additional information regarding immunosuppression in the CONTRAINDICATIONS section and additional post-marketing experience information in the ADVERSE REACTIONS section, and to revise the patient package insert labeling to include additional information regarding concomitant administration of Zostavax with inactivated influenza vaccines.

We hereby approve the draft package insert labeling submitted under amendment STN 125123/2102.1, dated March 19, 2018, and the patient package insert labeling submitted under STN 125123/2102, dated September 19, 2017.

Please provide your final content of labeling including the carton and container labels in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to BLA STN 125123 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in 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.

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 this change.

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

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research