



## SUPPLEMENT APPROVAL

OUR STN: BL 103552/6047

Merck Sharp & Dohme Corp.  
Attention: James J. Kollmar, M.D., F.A.A.P.  
One Merck Drive  
P.O. Box 100  
Whitehouse Station, NJ 08889-0100

**February 17, 2017**

Dear Dr. Kollmar:

We have approved your request dated April 22, 2016, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Varicella Virus Vaccine Live (VARIVAX®) manufactured at your West Point, PA (b) (4) facilities to include implementation of the (b) (4) method in the production of Varicella Zoster Virus (b) (4) for VARIVAX® Drug Substance manufacture.

We have also approved revisions to your package insert labeling to comply with the 2014 Final Rule, *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling*.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 02062502

We hereby approve the draft package insert labeling submitted under amendment 103552/6047.5010, dated February 16, 2017.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. All final labeling should be submitted as Product Correspondence to BLA 103552/0 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 these changes.

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