U.S. FOOD & DRUG ADMINISTRATION

SUPPLEMENT APPROVAL

Our STN: BL 103552/6113

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

October 19, 2018

Dear Dr. Saldutti:

We have approved your request dated April 20, 2018, 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, Pennsylvania (b) (4) facilities to revise the package insert to include the term "meningitis" in Section 6.2 Post-Marketing Experience and to clarify previously reported terms of "encephalitis" and "herpes zoster."

LABELING

We hereby approve the draft package insert labeling submitted under amendment 103522/6113/5000 dated October 17, 2018.

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.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on April 20, 2018 according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using*