



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

Our STN: **BL 125108/774**

**SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp.  
Attention: Donna Zacholski  
P.O. Box 1000, UG2D-68  
North Wales, PA 19454-1099

Dear Ms. Zacholski:

We have approved your request to supplement your biologics license application for Measles, Mumps, Rubella and Varicella Virus Vaccine Live, ProQuad<sup>®</sup>, manufactured at your West Point, PA facility, to include clinical data that support the safety and immunogenicity of refrigerator-stable and frozen formulations of ProQuad with (b) (4) per dose. These formulations are produced using the (b) (4)

The review of this product was associated with the following National Clinical Trial (NCT) number: NCT01536405.

We will include information contained in the above-referenced supplement in your biologics license application 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