



## SUPPLEMENT APPROVAL

OUR STN: BL 125122/1309

Merck Sharp & Dohme Corp.  
Attention: Paul L. Koser, Ph.D.  
1 Merck Drive  
P.O. Box 100  
Whitehouse Station, NJ 08889-0100

February 23, 2017

Dear Dr. Koser:

We have approved your request dated April 20, 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 Rotavirus Vaccine, Live, Oral, Pentavalent (RotaTeq™) to expand the indication to include prevention of rotavirus gastroenteritis caused by type G9.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 00718237.

### **LABELING**

We hereby approve the draft package insert labeling submitted under amendment 125122/1309.6, dated February 14, 2017.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to BLA 125122 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.

## **PEDIATRIC REQUIREMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to less than 6 weeks of age because:

- 1) the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group. This is because initiating vaccination at 0 through 5 weeks of age with RotaTeq would not provide a meaningful therapeutic benefit over initiating vaccination at 6 weeks of age.

We are waiving the pediatric study requirement for ages greater than 32 weeks to less than 17 years of age because:

- 2) the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group. Although older children may still be susceptible to rotavirus infections in the absence of immunity from prior exposure, the numbers of infections in these ages are small compared to those <5 years of age and the severity of the disease decreases with age.

We note that you have fulfilled the pediatric study requirement for ages 6 weeks to 32 weeks for this application.

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