

Dear Dana Harrison:

Dear Dana,

We are reviewing your Biologics License Application (BLA) dated March 24, 2014, for Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine and have determined that the following information regarding the Poliovirus (b) (4) protocol.

We note that the Internal quality control (IQC) reference ratio assay validity criterion will be removed from the Poliovirus (b) (4) protocol (Instruction Q_0278720) and replaced with an IQC titer acceptance range (125525/0.2; RED_00073615). Please confirm that supportive data will be submitted for review prior to the institution of this change.

Please promptly submit your written response so we may proceed with the review of your application.

Thanks you,

Juan

*Juan C. Lacayo, Ph.D.
LCDR, United States Public Health Service
Regulatory Reviewer/Project Manager
CMC Review Branch I
Division of Vaccines and Related Product & Applications
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
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