Dear Dana Harrison:

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 is necessary to take complete action. Please promptly submit your written response to the following items so that we may continue evaluating your BLA:

1. Please provide data to support the stability of the performance of the immunoassays used to assess responses to diphtheria, tetanus and pertussis from the time of validation to the analysis of samples in in study M5I02.

2. If you retested samples in your immunologic assays and replaced specific data points in study M5I02, please provide a summary of retesting either as part of the Clinical Study Report or separately. In this summary, we request you include a listing of the values replaced during data cleaning, reasons for sample retesting, and an assessment of the impact of the retesting and replacement of values.

3. Please provide the transfer protocols and reports for the anti-diphtheria and anti-tetanus assays described in Table 1 of Appendix 11 (Assay Techniques and Standard References) in Section 5.3.5.1, Inter Laboratory Standardisation Methods Quality Assurance.

If you have any questions, please contact the Regulatory Project Manager, Juan Lacayo, Ph.D., at (301) 796-2640.

Thanks,

juan

Juan C. Lacayo, Ph.D.

LCDR, United States Public Health Service

Regulatory Reviewer/Project Manager

CMC Review Branch 1

Division of Vaccines and Related Product & Applications

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

U.S. Food and Drug Administration

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