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:

- Please provide a list of all current manufacturing and testing sites, including the respective Facility establishment Identifier (FEI) numbers for both Drug substance (section 3.2.S.2.1) and Drug Product (section 3.2.P.3.1).

Please submit your response by **March 9, 2014**, so we may continue the review of your application.

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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