

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. With regard to the Poliovirus (b) (4), please provide data demonstrating assay stability (performance) since last validation.
2. With regard to the poliovirus component of the Lot Release Protocol, please confirm whether the changes to Tables 8 [Mycoplasma Testing (b) (4)] and 14 [Mycoplasma Testing (b) (4)] have been approved by CBER and if so reference the appropriate submission.
3. The following Information Requests pertaining to the poliovirus component of the Lot Release Protocol were previously relayed on June 18, 2014 for the Pentacel product. These also pertain to the QUADRACEL product. Please respond to these requests to both files.
 - a. In Table 1 “Poliovirus Monovalent Inactivated Testing”, please include the actual D antigen titer at the (b) (4) (for each poliovirus type) and the date for the (b) (4).
 - b. Please clearly define Off Test Date in the Lot Release Protocol. In the past, this date has corresponded to either date of test completion or date of sign off / approval.
 - c. In Table 2 “Poliovirus Trivalent Concentrate Lot Genealogy”, use of the terminology MRC-5 cells is ambiguous. Please revise the terminology to “MRC-5 Control Cells”.
 - d. In Table 11 “Poliovirus Vaccine Inactivated (b) (4)”, use of the terminology “Reference Vaccine (Positive Control)” is inappropriate. Please consider reverting this terminology to “Relative to Standard”.

- e. Tables 8 [Mycoplasma Testing (b) (4)] and 14 [Mycoplasma Testing (b) (4)] have not been reconfigured for poliovirus Type 2. Please explain.

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

Thanks you,

Juan

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