Dear Dana Harrison:

We are reviewing your Biologics License Application (BLA) 125525 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 your modified testing method for mycoplasmas (b) (4) we are concerned that you have not demonstrated the assay's ability to detect the necessary range of species relevant to your manufacturing process. Please include an additional assessment of the revised method to detect (b) (4) and submit the completed validation package as an amendment (CBE-30) to the Pentacel (125145) file and with appropriate cross reference to the Quadracel file (125525).

2. Please state the incubation environment and the temperature for the modified mycoplasma testing protocol in the relevant tables for (b) (4) contained in the updated lot release protocol.

3. We note that two statements ("The length of the initial incubation on (b) (4) " and (b) (4) , as outlined in your list of principal modifications to the mycoplasma test, are inconsistent with the information submitted in "Figure 2: Flow Chart for Modified Mycoplasma Culture Method Analytical Procedure". Please clarify.

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

Thanks you,

Juan

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