From: Campbell, Karen M
Sent: Monday, November 10, 2014 2:10 PM
To: Samuel.Shek@sanofipasteur.com
Cc: Arciniega, Juan Luis; Quander III, Joseph
Subject: RE: Sanofi Pasteur Pentacel LRP template for review

Dear Mr. Shek,

CBER has reviewed the information submitted to me by e-mail on October 21, 2014 for STN 125145 lot release protocol templates.
We have the following comments on the lot release protocol templates submitted in this e-mail.

1. Please state the actual (i.e. experimentally determined) and the calculated D-antigen value for each poliovirus monovalent at the (b) (4) in Table 1 "Poliovirus Monovalent Inactivated Testing" (Page 3/18 for each poliovirus monovalent in the updated lot release protocol).
2. In Table 11 "Poliovirus Vaccine Inactivated (b) (4) " (Page 23 of 46) of the updated lot release protocol, please amend "Acceptance Criteria: (b) (4) " to "Acceptance Criteria: (b) (4) for each Poliovirus Type relative to Standard Lot". In addition please include the expiry date for the Standard Lot in Table 11.
3. On page 16 of 46 of the Final Bulk template, please add the (b) (4) test date.

Regarding the questions on the pertussis section of the lot release protocol, CBER has the following responses:

1. CBER agrees with SP's proposal to remove the (b) (4) reports for the pertussis antigens, and provide only an overall summary of data results in the LRP.
2. CBER agrees with SP's proposal to remove the data reports for the acellular pertussis (aP) vaccine mouse immunogenicity (potency) test, and provide only the overall summary of results.

This decision impacts all SP vaccines containing an aP component, those already licensed: DAPTACEL (STN 103666), Adacel (STN 125111) and Pentacel (STN 125145) and those on the road to licensing: Quadracel (STN 125525) (b) (4) . CBER requests that you send the updated lot release protocols for the licensed vaccines, DAPTACEL (STN 103666), Adacel (STN 125111) and Pentacel (STN 125145) to the sample custodian (Joe Quander) for approval of the changes.

Sincerely,

Karen Campbell
Regulatory Coordinator
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