

Mid-cycle Communication Telecon

Application type and number: Original Application, STN 125525/0

Product name: Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine (Quadracel)

Proposed Indication: Immunization against diphtheria, tetanus, pertussis and poliomyelitis, ages 4-6 years.

Applicant: Sanofi Pasteur Ltd.

Meeting date & time: September 19, 2014 at 1PM EST

Committee Chair: LCDR Matthew Steele, PhD

RPM: LCDR Juan Lacayo, PhD

CBER Attendees:

LCDR Matthew Steele PhD, Chair

LCDR Juan Lacayo PhD, RPM

LCDR Kelsy Hoffman PhD

Marion Gruber PhD, Director, Office of Vaccines Research and Review

Wellington Sun MD, Director, Division of Vaccines and Related Products Applications

Christopher Sese, Contractor, Eastern Research Group

Discussion Summary:

1. Any significant issues identified by the review committee to date

The applicant was queried on when we might expect a finalized lot release protocol, as discussed with Dr. Juan Arciniega on September 17, 2014.

The applicant stated that they expected to submit a revised lot release protocol to the Pentacel[®] BLA by the end of September, 2014. A finalized version was expected to this application by mid-October, 2014.

2. Information regarding major safety concerns

At this time, the review committee has not identified any major safety concerns.

3. Preliminary review committee thinking regarding risk management

At this time, we do not anticipate the necessity of a REMS, PMR or PMC.

4. Any information requests sent and not received.

The sponsor stated that they would send a reply to our IR of September 12, 2014 in mid-October, along with the revised lot release protocol. This IR would also contain a description of their cross-reference strategy which we requested a communication on May 13, 2014.

5. Any new information requests to be communicated:

At this time, we have no additional Information Requests to convey.

6. Proposed date(s) for the late-cycle meeting

We propose the date of December 3rd, at 1 PM EST.

7. Updates regarding plans for the AC meeting

We have no plans at this time to discuss this application at an Advisory Committee meeting.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates

This application has the following milestone dates:

Late Cycle Meeting: To be held by December 7, 2014.

Labeling Comments: To be submitted to you no later than February 22, 2015

Action Due: We will take action on this application no later than March 24, 2015