

Mid-Cycle Communication Telecon

Application type and number: Original Application, STN125563/0

Product name: Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, *Haemophilus b* Conjugate and Recombinant Hepatitis B Vaccine

Proposed Indication: Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive *Haemophilus influenzae* type b disease in infants and children 6 weeks through 4 years of age (prior to fifth birthday)

Applicant: MCM Vaccine Company

Meeting date & time: February 06, 2015 1:00PM

Committee Chair: Rana Chattopadhyay, Ph.D.

RPM: Kelsy Hoffman, Ph.D./ Katie Rivers, M.S.

CBER Attendees:

Rana Chattopadhyay, Ph.D., Chair

Kelsy Hoffman, Ph.D, RPM

Katie Rivers, M.S., RPM

Jennifer Bridgewater, M.P.H., Regulatory Coordinator

Wellington Sun, M.D., Division Director

Christopher Sese, Contractor, Eastern Research Group

Patrick Zhou, Contractor, Eastern Research Group

Sponsor Attendees:

Merck:

Steve Dziennik, Director, Manufacturing Division

Beth Arnold, Director, Vaccine Clinical Assays

Angela Ngai, Director, Clinical Research

Jin Xu, Associate Director, Biostatistics

Frank Liu, Director, Biostatistics

Susan VanRheenen, Associate Director, Project Management

Andrew Wen-Tseng Lee, Director, Clinical Research and Project Leader

Morgan Marks, Associate Director, Pharmacoepidemiology

Patricia Saddier, Executive Director, Pharmacoepidemiology

Paul Koser, Director, Regulatory

Charles Kline, Associate Director, CMC Regulatory

Leonidas Drogaris, Director, Clinical Safety and Risk Management

Annie Chen, Executive Director, Clinical Research

Sanofi Pasteur:

Erin Keyes, Deputy Director, IO/Manufacturing Technology

Juthika Menon, Senior Scientist, IO/Manufacturing Technology

Liane Smith, Director, IO/Manufacturing Technology

Krissy Carrington, Deputy Director, Regulatory Affairs

Ellen Snell, Deputy Director, R&D Project Management

Bill Flounders, Senior Director, R&D Project Leadership

Celine D'Souza, Manager, Regulatory Affairs Labelling

Fotula Fegaras, Senior Director, Regulatory Affairs
Dhaval Patel, Research Scientist, Global Clinical Immunology
Emelia Jordanov, Senior Director, Clinical Development

Discussion Summary:

CBER provided the Mid-Cycle Communication (plain and bold text below) to the Applicant on February 4, 2015. Discussion between CBER and the Applicant during the Mid-cycle Communication is included below in italics.

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

There are no significant issues/major deficiencies identified at this time.

2. Information regarding major safety concerns.

There are no major safety concerns identified at this time.

3. Preliminary review committee thinking regarding risk management.

We do not anticipate the necessity for Postmarketing Requirements (PMRs) or a Risk Evaluation Mitigation Strategy (REMS) at this time.

The applicant questioned if CBER could convey any preliminary communication regarding REMS and if CBER could confirm that there would not be post-approval safety requests. CBER indicated that no post-approval safety requests are anticipated at this time; however, the review is still ongoing.

4. Any information requests sent and not received

We have received responses to all information requests communicated to date.

5. Any new information requests to be communicated

We anticipate requests for additional chemistry, manufacturing, and control information as well as some statistical comments.

The applicant questioned and CBER confirmed that the currently anticipated statistical comments are clinical in nature. The applicant inquired if the CMC information requests will be sent on a rolling basis and CBER confirmed that requests for additional information will be sent on an as needed basis throughout the review process.

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

The LCM between you and the review committee is currently scheduled for May 5, 2015. We intend to send the meeting materials to you no later than 12 business days in advance

of the LCM. If these timelines change, we will communicate updates to you during the course of the review.

7. Updates regarding plans for the Advisory Committee (AC) meeting

We do not anticipate the need for an AC meeting at this time.

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

Late Cycle Meeting: To be held on May 5, 2015

Labeling Comments: To be submitted to you no later than July 10, 2015

Action Due: We will take action on this application no later than August 12, 2015

CBER noted that the Mid-cycle communication to the Applicant has been recently implemented with PDUFA V and advised that the applicant consider the Mid-cycle communication document sent prior to the communication to determine the required applicant attendees.