

Meeting Summary

Application type and number: Biological Licensure Application (BLA), Original Submission (OS)

Product name: (b) (4) 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: October 7, 2015 3:00PM-4:00PM

Committee Chair: Rana Chattopadhyay, Ph.D.

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

CBER/FDA Attendees:

Rana Chattopadhyay, Ph.D., Chair, DVRPA/OVRR

Katie Rivers, M.S., Regulatory Project Manager, DVRPA/OVRR

CAPT Ann Schwartz, M.D., Medical Officer, DVRPA/OVRR

Jennifer Bridgewater, M.P.H., Regulatory Coordinator, DBPAP/OVRR

Juan Arciniega, Ph.D., CMC Reviewer, DBPAP/OVRR

Michael Schmitt, Laboratory Chief/CMC Reviewer, DBPAP/OVRR

Drusilla Burns, Ph.D., Deputy Division Director, DBPAP/OVRR

Douglas Pratt, M.D., M.P.H., Associate Director for Medical Affairs, DVRPA/OVRR

Wellington Sun, M.D., Division Director, DVRPA/OVRR

Karen Farizo, M.D., Associate Office Director for Medical Policy and Vaccine Safety, OVRR

Philip Krause, M.D., Deputy Office Director, OVRR

Marion Gruber, Ph.D., Office Director, OVRR

Summary:

Responses to the CBER's comments regarding the Pertactin (PRN) Potency assay were provided in the October 1, 2015 amendment (STN125563/0/22). Data from Table 4 provides testing data for the (b) (4) most recently produced commercial scale lots of PR5I ((b) (4) U.S. lots and (b) (4) EU lots: EU lots are made with same (b) (4) as U.S. lots). Of the (b) (4) lots tested, 3 were OOS (1 on stability and 2 at release) and two lots had stage 1 failures at release. Only 2 out of (b) (4) lots passed release testing without stage 1 failures (both were U.S. lots). U.S. lots (b) (4) were made with (b) (4) used for the other four lots was not provided. The applicant indicates that the root cause is (b) (4) manufactured between May-Nov 2014. The investigation is ongoing, and a completion date for the investigation is projected for the 3rd quarter of 2016. Production of the first commercial scale lots using (b) (4) is projected for the 2nd quarter of 2017. Since the applicant has not provided results from the OOS investigation, nor shown that product can currently be manufacture to consistently demonstration PRN potency, the discipline review team members

that were present and upper management agreed that a CR is necessary. In the CR letter, CBER will request:

- a. The complete results from the OOS investigation.
- b. Information and testing data demonstrating that commercial scale lots of (b) (4) can be consistently manufactured with the same PRN testing profiles as those clinical lots used in the pivotal trials and that commercial scale lots retain the same PRN potency testing profiles throughout the proposed expiration dating period.