

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: June 4, 2015 11:00AM-12:00PM

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

LCDR Kelsy Hoffman, Ph.D., Regulatory Project Manager, 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

Loris McVittie, Ph.D., Deputy Division Director, 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:

The purpose of this meeting was to discuss a possible Complete Response (CR) for BLA 125563/0. Data from Tables 3, 4, and 5 in Section 1.11.1 of BLA amendment STN 125563/0.8 (submitted May 19, 2015) were discussed. These tables show results of (b) (4)

release, stability and accelerated stability tests for PR5I lots filled into vials (b) (4)

of these tests yielded Out of Specification (OOS) results when using the specification that was used for the release and stability assessment of the clinical lots (b) (4)

tested). (b) (4) of these tests would remain OOS even if the acceptance criterion for the test were revised to (b) (4) tested, as the Applicant requested.

Since the Applicant has neither identified a definitive root cause for these out of specification results, nor shown that the problem that led to this outcome has been resolved, the discipline review team members that were present and upper management agreed that a CR is necessary.

In the CR letter, CBER will request supportive data and information to demonstrate that the (b) (4) testing is operating under a state of control, that the production lots of PR5I have the same (b) (4)

profile as lots that were shown to be safe in the clinic, and that these lots would be expected to retain that profile throughout their dating period.