

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125563/0 Office: OVR

Product: Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B [Recombinant] Vaccine - (b) (4)

Applicant: MCM Vaccine Company (MCM)

Telecon Date/Time: 21-Apr-2015 11:00 AM Initiated by FDA? Yes

Communication Category(ies): Advice

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Telecon Summary:

CBER sent an information request (IR) regarding the (b) (4) results submitted to the BLA on February 23, 2015. MCM responded on April 9, 2015 (125563/0.6). A follow-up IR was sent to MCM on April 17, 2015. The purpose of this telecon is to provide clarification regarding the follow-up IR.

FDA Participants:

Katie Rivers
Jennifer Bridgewater
Tina Roecklein
Rana Chattopadhyay
Juan Arciniega
Drusilla Burns
Michael Schmitt
Tod Merkel

Non-FDA Participants:

MCM Vaccine Company

Sanofi Pasteur

Ms. Meaghan Fowler, Scientist, Analytical Process & Technology
(b) (4), Scientific Consultant, Analytical Process & Technology
Dr. Juthika Menon, Senior Scientist, Analytical Process & Technology
Dr. Susan Nelson, Director, Analytical Process & Technology
Mr. Jason Yip, Deputy Director, Biostatistics, Quality Operations
Dr. Olivier Faure, Director, Quality Operations
Mr. Lenzi Bourdeau, Manager, CMC Regulatory Affairs, SP
Mrs. Maureen Barbalinardo, Deputy Director, CMC Regulatory Affairs, SP
Mrs. Krissy Carrington – Deputy Director, Regulatory Affairs, SP
Mr. William Flounders – Senior Director, Project Leadership, SP

Merck

Dr. Paul Koser – Director, Regulatory Affairs Vaccines, MRL

Mr. Charles Kline – Associate Director, Regulatory Affairs CMC, Vaccines, MRL
Dr. Andrew Lee – Director and Project Leader, Clinical Research Vaccines, MRL

Telecon Body:

CBER stated that the purpose of this telecon is to provide any required clarification regarding the follow-up (b) (4) assay IR comments that were sent to MCM on April 17, 2015. MCM stated that the proposed change in (b) (4) specification (from (b) (4) for the clinical lots to (b) (4) for the commercial lots) is based on the results obtained and re-analysis that have been completed and asked for CBER comment. CBER responded that a determination regarding the change in specification will be based on complete data and the pending responses to CBER's request for additional information.

MCM stated that they are in the process of compiling responses to the April 17, 2015 information request and asked to provide additional information to CBER in the form of a presentation in the next two weeks. CBER responded that holding another meeting to discuss this topic in two weeks is premature in that they would first need to receive and review written responses to CBER's information request. CBER requested that MCM submit responses as an amendment to the BLA as soon as possible. MCM stated that they are concerned because multiple investigations are ongoing and they may only be able to respond to some of the April 17, 2015 comments at this time. CBER indicated that the sponsor could provide written response to the comments as the information becomes available. CBER stressed that it would be especially important to receive, as soon as possible, a timeline indicating when the information requested by CBER will be submitted. CBER agreed that, once CBER has received and reviewed the information that is currently available as well as the timeline for submission of the remaining responses, future discussion or a potential presentation from MCM may be necessary to keep CBER informed regarding the ongoing investigations. MCM stated that they intend to put together a written response to submit on April 24, 2015 because the late cycle meeting (LCM) is scheduled for May 5, 2015. CBER stated that it is unlikely that this issue will be addressed before the LCM and that CBER will work to review the information submitted in a timely manner.