

RECORD OF TELEPHONE CONVERSATION

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

Product: Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine

Applicant: MCM Vaccine Company

Telecon Date/Time: 17-Feb-2015 10:59 AM Initiated by FDA? Yes

Communication Category(ies):

1. Information Request

Author: KATIE RIVERS

Telecon Summary: Emailed Information Request regarding blank COAs and stability protocols for Pentacel and ActHIB

FDA Participants: Kelsy Hoffman, Katie Rivers

Non-FDA Participants: Krissy Carrington

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Rivers, Katie

Sent: Tuesday, February 17, 2015 10:59 AM

To: krissy.carrington@sanofipasteur.com

Cc: Hoffman, Kelsy

Subject: Request for additional information

Dear Ms. Carrington,

We have the following request for additional information regarding your BLA, STN125563/0:

1. The following request pertains to Pentacel:
 - a. Blank certificates of analysis (COAs) for final formulated bulks and final containers of Pentacel (DTaP-IPV and Hib bulks and final containers and reconstituted product)
 - b. Stability protocol for Pentacel
2. We acknowledge that (b) (4) does not contain PRP-T, however, please provide the following information pertaining to ActHIB:
 - a. Blank certificates of analysis (COAs) for final formulated bulks and final containers of ActHIB
 - b. Stability protocol for ActHIB

Please submit the above information as an amendment to STN125563/0.

Please let me know if you have any questions.

Thank you,

Katie

Katie H. Rivers, M.S.

Regulatory Project Manager, RRB1

FDA/CBER/OVRR/DVRPA

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