

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 Categorie(s):
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

10903 New Hampshire Ave., HFM-481

Silver Spring, MD 20993-0002

Phone 301-796-2640

Fax 301-595-1244

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.