

From: Krissy.Carrington@sanofi.com [mailto:Krissy.Carrington@sanofi.com]
Sent: Monday, July 23, 2018 12:49 PM
To: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: RE: STN 125563 Advice and Information Request

Dear Kelsy,
Acknowledging receipt of this IR. Kind regards,
Krissy

From: Hoffman, Kelsy [mailto:Kelsy.Hoffman@fda.hhs.gov]
Sent: Monday, July 23, 2018 12:20 PM
To: Carrington, Krissy /CA
Subject: [EXTERNAL] STN 125563 Advice and Information Request

Dear Ms. Carrington,

Please note that BLA 125563/0, "Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine," cannot be approved until a complete response is received for the companion For Further Manufacturing Use (FFMU) applications that you cross-reference for information regarding the Haemophilus b Conjugate (Meningococcal Protein Conjugate) Bulk Intermediate and Hepatitis B Vaccine (Recombinant) Bulk Intermediate.

Also, we note that although cross-reference authorization letters were submitted to FFMU BLAs 125580/0 and 125581/0 for BLA 125563/0, cross-reference letters to the FFMU BLAs were not officially submitted to BLA 125563/0. Please submit official cross-reference letters under module 1.4 of your BLA.

Please let me know if you have any questions.

Thank you,
Kelsy

Kelsy F. Hoffman, Ph.D.
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