

From: Krissy.Carrington@sanofipasteur.com [mailto:Krissy.Carrington@sanofipasteur.com]
Sent: Friday, September 18, 2015 8:05 AM
To: Rivers, Katie
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: RE: Request for additional information - STN125563/0

Dear Katie

Thank you for the email. Just a quick update that I will be able file the e-sequence to the eBLA this afternoon. Kind regards,
Krissy

From: Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]
Sent: Friday, September 18, 2015 7:16 AM
To: Carrington, Krissy (sanofi pasteur)
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: Request for additional information - STN125563/0

Dear Ms. Carrington,

We have the following request for additional information regarding BLA125563/0:

Please provide PRN Immunogenicity (Mouse) release and stability product data including Phase 3 lots and any commercial lots for any market [tested by the US method], available to date. Please comment on the (b) (4) pertussis immunogenicity (mouse) justification of specifications.

Please provide a response no later than 2:00 PM on September 23, 2015.

Thank you,
Katie

Katie H. Rivers, M.S.
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