

From: Krissy.Carrington@sanofipasteur.com
To: [Rivers, Katie](#)
Cc: [Hoffman, Kelsy](#); [Chattopadhyay, Rana](#)
Subject: RE: Additional information regarding the (b) (4)
Date: Friday, June 05, 2015 2:33:37 PM

Dear Katie,

I acknowledge your request and confirm we are on track to achieve this submission no later than Jun 25, 2015. Kind regards,
Krissy

From: Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]
Sent: Friday, June 05, 2015 2:13 PM
To: Carrington, Krissy (sanofi pasteur)
Cc: Hoffman, Kelsy; Chattopadhyay, Rana
Subject: Additional information regarding the (b) (4)

Dear Ms. Carrington,

As stated during the Late Cycle Meeting (May 5, 2015) for STN125563/0, you will provide additional information regarding the ongoing investigation of the (b) (4) by the end of June. Please submit this information as an amendment to your BLA no later than June 25, 2015 to allow CBER sufficient time for review.

Thank you,
Katie

Katie H. Rivers, M.S.
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