

From: Krissy.Carrington@sanofipasteur.com
To: [Rivers, Katie](#)
Cc: [Hoffman, Kelsy](#)
Subject: RE: Information Request for BLA125563/0
Date: Wednesday, March 11, 2015 11:50:40 AM

Dear Katie

I acknowledge this additional information request. Kind regards,
Krissy

From: Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]
Sent: Wednesday, March 11, 2015 11:40 AM
To: Carrington, Krissy (sanofi pasteur)
Cc: Hoffman, Kelsy
Subject: Information Request for BLA125563/0

Dear Ms. Carrington,

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

With regard to the clinical serological information contained within IND14668, and cross-referenced in support of the PR5I BLA, please indicate when the (b) (4) testing was performed on the clinical samples for pivotal studies V419-005 and V419-006.

Please let me know if you have any questions.

Thank you,
Katie

Katie H. Rivers, M.S.
Regulatory Project Manager, RRB1
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