

From: Krissy.Carrington@sanofipasteur.com [mailto:Krissy.Carrington@sanofipasteur.com]
Sent: Wednesday, September 02, 2015 10:11 AM
To: Rivers, Katie
Subject: RE: Information Request STN125563/0

Dear Katie

I acknowledge this receipt of this request and confirm our commitment to provide this summary and revised sections as detailed below. I will include this with the response to CBER questions IR dated 27 Jul 2015. Kind regards,
Krissy

From: Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]
Sent: Wednesday, September 02, 2015 9:18 AM
To: Carrington, Krissy (sanofi pasteur)
Subject: Information Request STN125563/0

Dear Ms. Carrington,

We have the following request regarding STN 125563/0:

The release and stability monitoring acceptance criteria for several tests have been revised during the course of the review of the application. Therefore, we request that you revise section 3.2.P.5.1 *Specifications* to include a summary of all specification changes and update the table in this section as appropriate. Similarly, please update section 3.2.P.8.2 *Post-approval Stability Protocol and Stability Commitment* to include updated acceptance criteria in Table 4, as requested in our email of June 19, 2015, comment 3.

Please let me know if you have any questions.

Thank you,
Katie

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