

**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

Katie H. Rivers, M.S.  
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