

**From:** [Krissy.Carrington@sanofipasteur.com](mailto:Krissy.Carrington@sanofipasteur.com)  
**To:** [Rivers, Katie](#)  
**Cc:** [Hoffman, Kelsy](#)  
**Subject:** RE: Request for additional information - BLA125563/0  
**Date:** Wednesday, April 22, 2015 4:11:08 PM

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Dear Katie,

I acknowledge the receipt of this additional IR letter. Kind regards,  
Krissy

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**From:** Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]  
**Sent:** Wednesday, April 22, 2015 2:45 PM  
**To:** Carrington, Krissy (sanofi pasteur)  
**Cc:** Hoffman, Kelsy  
**Subject:** Request for additional information - BLA125563/0

Dear Ms. Carrington,

We have the following requests for additional information regarding clinical data submitted to STN125563/0:

Regarding studies PR505 and PR506:

1. We note that for each of the studies, Table 10-1 includes the category of “withdrawal by subject” during the time intervals of the studies. Please provide a narrative or reason explaining why each subject was discontinued or withdrew from the study.
2. Please provide a narrative for all subjects in both studies who were withdrawn from the studies due to “physician’s decision”.
3. Please provide more information on the clinical site and the number of subjects who received vaccines out of temperature range, including the identity of the vaccines received.
4. Please provide information on the occurrence of adverse events which occurred within 30 minutes following any vaccination for both studies.

Regarding study PR505:

5. Please provide narratives (to include time since last vaccination) for the six serious adverse events occurring Day 1-180 that included seizure and/or pyrexia for subjects following infant vaccinations.
6. For subject (b) (6) who developed pertussis beginning at day 165 post the third vaccination, please provide information on how pertussis was diagnosed and any further evaluations that were performed to confirm the diagnosis.

Regarding study PR506:

7. We note that nine subjects in PR506 were “cross-treated” during the conduct of the study. Please provide a summary table showing the original group randomization for each subject and the actual treatment received.
  
8. Table 12-2 (page 171) we note that 7 subjects discontinued the study due to an adverse event following infant vaccination. Please provide a summary of reasons for discontinuation for each of these subjects. It appears from the summary table that 1 subject discontinued due to a vaccine related adverse event, three subjects discontinued due to serious adverse events. The discontinuation reasons for the remaining three subjects are unclear. Please provide additional information.

Please let me know if you have any questions.

Thank you,  
Katie

Katie H. Rivers, M.S.  
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