

From: Rivers, Katie
Sent: Friday, October 16, 2015 1:44 PM
To: krissy.carrington@sanofipasteur.com
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: Request for additional information - STN125563/0

Dear Ms. Carrington,

We have reviewed your May 27, 2015 and August 21, 2015 amendments to STN 125563/0 and have the following comment in reference to the (b) (4) D-antigen (b) (4) used to assess potency of (b) (4) Product lots:

1. Although you indicate that the (b) (4) was validated to provide a reliable result based on testing of the single sample in triplicate without imposing rules for inter-replicate values, we recommend that you establish such a criterion to provide additional assurance of assay performance and precision of the reported result. We acknowledge that additional data will be required to establish the requested criterion. Please commit to providing this information as soon as possible.

Please respond no later than October 22, 2015.

Please let me know if you have any questions.

Thank you,
Katie

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