

From: Krissy.Carrington@sanofipasteur.com [mailto:Krissy.Carrington@sanofipasteur.com]
Sent: Friday, June 19, 2015 11:13 AM
To: Rivers, Katie
Cc: Hoffman, Kelsy; Chattopadhyay, Rana
Subject: RE: Information Request for STN125563/0

Dear Katie

I acknowledge receipt of this IR letter. Kind regards,

Krissy

From: Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]
Sent: Friday, June 19, 2015 9:31 AM
To: Carrington, Krissy (sanofi pasteur)
Cc: Hoffman, Kelsy; Chattopadhyay, Rana
Subject: Information Request for STN125563/0

We are reviewing STN 125563 for your PR5I (b) (4) vaccine and have the following requests for information.

The following comments pertain to the D-Antigen (b) (4) and Rat Immunogenicity Test information submitted on 27 May 2015 (SN 9):

1. With regard to (b) (4) D-antigen (b) (4) used at the (b) (4) Product stage:
 - a. Provide data demonstrating the adequacy of using only a single sample (tested in triplicate) of the PR5I (b) (4) product to determine its D-antigen content.
 - b. Please identify any validity criteria imposed on triplicate values observed from each sample tested (e.g., coefficient of variation, standard deviation, range, etc.).
2. With regard to the Rat Immunogenicity test, please provide the D-antigen content results for the reference vaccine lot (b) (4) and provide details showing how the correction factors (CF) were calculated and established.

The following comment pertains to the stability information provided on 28 May 2015 (SN10):

3. The stability protocol for routine commercial monitoring of the PR5I vaccine provided in Section 3.2.P.8.2 – Post-approval Stability Protocol and Stability Commitment, Table 4 does not include the acceptance criteria for the stability tests. Please include the acceptance criteria for each test in Table 4.

The following comment pertains to the impurities in the PR5I vaccine:

4. We note that (b) (4) protein and Polysorbate 80 were not included in the list of impurities for the PR5I vaccine (Section 3.2.P.5.5 - Characterization of Impurities, Table 1) and were not mentioned in the response to Question 3 in your submission of 20 April 2015 (SN 7). Please update Table 1 to include these and any other impurities from the

manufacturing process. For the (b) (4) and Polysorbate 80 please clarify if the amounts of these residual components are tested on the drug substance. Please provide the amounts of these impurities in the final bulk product and show how these amounts are calculated.

The following comment pertains to the validation of quality control tests:

5. For all non-compendial tests performed for PR5I final bulk product and filled product release and stability please identify the following:
 - a. The laboratory sites where these tests will be performed.
 - b. The laboratory sites where validation of these tests was performed.

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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