

From: Ramachandran, Girish
Sent: Monday, November 26, 2018 1:06 PM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: Information Request for BLA125563

Dear Ms. Mayer,

We have the following information request for your BLA125563.

The following comment pertains to the Rat Immunogenicity Test for IPV potency submitted in Amendment 33 (SN 33 dated April 23, 2018):

1. We do not agree with discontinuation of correction factor use. Although at the time of reassessment of (b) (4) potency (date not stated), Type 1, 2, and 3 correction factors were close to (b) (4), the data shown in Figure 9 in document "Reference Standards or Materials Stability Data" (eCTD Section 3.2.P.6, Stability Data, pages 14 of 16) predict that the Type 1 and Type 3 potencies of (b) (4) will continue to decay. If your projections are correct, the correction factors will substantially deviate from (b) (4) in the near future, necessitating to reemploy correction factors. Please provide a plan for more frequent monitoring of (b) (4) potency in order to employ periodically adjusted correction factors.

The following comments pertain to the D-Antigen (b) (4) for IPV potency submitted in Amendment 44 (SN 46 dated October 26, 2018) in responses to our information request of October 15, 2018:

2. With regard to Reference Standard lot (b) (4) :
 - a. We note that the potency values determined for this material as reported in this submission for the Toronto site are different from the values determined for the same material at the MLE site as reported in STN 103930/5234. Please explain.
 - b. Please provide the qualification report for reference lot (b) (4) . If the qualification study was not performed at the Toronto site, please provide data demonstrating acceptable performance of the reference material at the Toronto site. Such data should include a comparison of the D-antigen content of an appropriate number of production lots when tested using the current reference lot (b) (4) versus lot (b) (4) .

Could you please send us your response by Friday November 30th?

Best,
Girish

Girish Ramachandran, Ph.D.

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