

From: Krissy.Carrington@sanofipasteur.com [mailto:Krissy.Carrington@sanofipasteur.com]
Sent: Monday, September 21, 2015 4:23 PM
To: Hoffman, Kelsy
Cc: Chattopadhyay, Rana; Rivers, Katie
Subject: RE: BLA 125563/0 Information Request

Dear Kelsy,

I appreciate CBER's time today to review these comments and acknowledge receipt of the IR letter and deadline. Kind regards,
Krissy

From: Hoffman, Kelsy [mailto:Kelsy.Hoffman@fda.hhs.gov]
Sent: Monday, September 21, 2015 4:07 PM
To: Carrington, Krissy (sanofi pasteur)
Cc: Chattopadhyay, Rana; Rivers, Katie
Subject: BLA 125563/0 Information Request

Ms. Carrington,

CBER is very concerned regarding the recent OOS results obtained for the PRN Mouse Immunogenicity Assay for PR5I. We have the following comments regarding these OOS results:

1. In your submission on September 18, 2015, you describe (b) (4) new lots of PR5I: (b) (4) . Please provide information on the (b) (4) of the batches of AIPO used to produce each of these lots (b) (4)].
2. Please indicate when the investigation into the PRN OOS results for PR5I will be submitted to CBER.
3. Please indicate when new lots of PR5I will be manufactured that utilize AIPO that has (b) (4) .
4. We note in Table 6 that lot (b) (4) was produced by EU MAA specifications. Please indicate the differences between lot (b) (4) and PR5I lots manufactured according to the US eBLA specifications. In particular, please indicate if there is a difference in the AIPO that is used to produce these lots [(b) (4) and US eBLA PR5I lots].

Please provide responses to these comments no later than September 30, 2015.

Thank you,
Kelsy

Kelsy F. Hoffman, Ph.D.
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