

From: Ramachandran, Girish
Sent: Thursday, September 27, 2018 5:25 PM
To: Kristen.Mayer@sanofi.com
Cc: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: STN 125563 Information Request

Dear Ms. Mayer,

With regard to BLA 125563, we have the following request for additional information:

We have the following comments regarding the information you provided in amendment 38 (SN39 dated 21 August 2018) in response to our information request of 14 June 2018:

The following comment pertains to your response to Comment 2:

- Regarding the acceptance limits for the IPV components, we note that the proposed lower limits are lower when reporting potencies using the (b) (4) method than the corresponding limits for Pentacel using the (b) (4) method. Therefore, we request that the lower limits for the IPV components in PR5I be revised to reflect the lower limits for Pentacel as close as possible. One approach could be to apply conversion factors as you relayed previously (e.g., (b) (4), for poliovirus Types 1, 2, and 3, respectively), if applicable in this situation.

The following comment pertains to your response to Comment 3:

- In your response to Q3 you indicated, "...the D-antigen contents indicated in the Product Information for PR5I US is based on the (b) (4) method (29, 7, 26 DU/dose) whereas the D-antigen content indicated in the Product Information for PR5I Europe (40, 8 and 32 DU/dose) is based on the method used for the (b) (4) method). However, the (b) (4) used for PR5I US and PR5I EU are identical and strictly formulated and tested for D-antigen content in the same way using the same acceptance criteria." We understand that the (b) (4) are tested using the (b) (4) method for PR5I released in the US and EU; however, the calculation method used on the PR5I (b) (4) Product (i.e., (b) (4) Filled Product released in the EU is not clear. Please clarify which D-antigen (b) (4) calculation method is used on the drug product steps ((b) (4) Filled Product, as applicable) for release of PR5I vaccine in the EU and provide the acceptance limits.

Could you please send us your response for the IR within the next 7 days? If you would like to discuss the above comments with CBER reviewers, please do not hesitate to contact me.

Thanks,

Girish

Girish Ramachandran, Ph.D.

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