

From: Krissy.Carrington@sanofipasteur.com [mailto:Krissy.Carrington@sanofipasteur.com]

Sent: Wednesday, September 09, 2015 11:05 AM

To: Rivers, Katie

Subject: RE: STN BLA 125563: PR5I Vaccine, (b) (4) and IR Follow-up Information

Dear Katie,

Thank you for providing this information. I will incorporate this information into the 27 Jul 2015 IR response/02 Sep request for specification revision tables and update Module 3 sections. Kind regards,

Krissy

From: Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]

Sent: Wednesday, September 09, 2015 10:55 AM

To: Carrington, Krissy (sanofi pasteur)

Subject: RE: STN BLA 125563: PR5I Vaccine, (b) (4) and IR Follow-up Information

Dear Ms. Carrington,

We have reviewed your September 4, 2015 amendment to STN125563/0 and have the following recommendations regarding the (b) (4)) discussed in the July 15, 2015 e-mail and July 24, 2015 teleconference:

1. The release specification for the (b) (4) test will be (b) (4)
2. At this time we agree to a dating expiry period of no more than 42 months for (b) (4)
3. (b) (4) commercial scale lots of (b) (4) per year should be put on the stability program, for at least three years. After data are accrued and reviewed for those (b) (4) lots, the results will be evaluated by CBER and the decision to test only one lot per year on the stability program may be made in consultation with CBER. Please acknowledge.

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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From: Krissy.Carrington@sanofipasteur.com [<mailto:Krissy.Carrington@sanofipasteur.com>]

Sent: Wednesday, September 02, 2015 10:20 AM

To: Rivers, Katie

Subject: RE: STN BLA 125563: PR5I Vaccine, (b) (4) and IR Follow-up Information

Hi Katie,

Could you provide me with an email to confirm CBER's final position on the expiry dating and post-approval commitment. I am in the process of finalizing the responses to the 27 Jul 2015 IR letter and will need this information to finalize the 3.2.P.5 and 3.2.P.8 sections. Thanks so much for your help. Kind regards,

Krissy

From: Carrington, Krissy (sanofi pasteur)

Sent: Friday, August 28, 2015 5:50 PM

To: Rivers, Katie (Katie.Rivers@fda.hhs.gov); Hoffman, Kelsy (Kelsy.Hoffman@fda.hhs.gov)

Cc: Chattopadhyay, Rana (Rana.Chattopadhyay@fda.hhs.gov)

Subject: STN BLA 125563: PR5I Vaccine, (b) (4) and IR Follow-up Information

Reference STN BL 125563

Re: DTaP-IPV-Hib-Hep B/PR5I Vaccine – (b) (4) Information

Dear Katie, Kelsy,

I am providing the following information via email in order to meet the timeline committed to you 24 Jul 2015 and status update dated 17 Aug 2015.

As requested during the 24 July 2015 teleconference held between Sanofi Pasteur and CBER, an amendment to STN BL 125563 DTaP-IPV-Hib-HepB / PR5I is being filed to include additional (b) (4) re-test results in (b) (4) mice only.

Following review of this information, I appreciate if I could receive via email CBER's final position on the product expiry dating and post-approval stability commitment. (This will facilitate the finalization of the Sponsors' cGMP documentation. We intend to update any impacted (b) (4) with the 27 Jul 2015 CMC response).

Please note, additionally within this e-amendment, we are providing a correction notice for the (b) (4) Investigation Report submitted on 25 June 2015 (Sequence 0012). The notice summarizing the corrections made to the report is provided in the attached file "01_358-PR5I Correction Notice 25 Jun 2015 Section 1.11.1 (US) Quality Information Amendment". We are also providing a corrected report. This report is being provided to ensure accuracy and completeness of the BLA file. Importantly, no

conclusions are impacted as a result of this update. I apologize for the inconvenience this may cause the reviewers but wanted to inform you of the correction presented to me during the approval of cGMP documentation/report and to update the associated license documentation.

The official e-amendment will be transmitted via ESG 01 Sep 2015. I will also send the remaining response from the 19 Jun 2015 CMC IR letter (Question 05) via ESG 01 Sep 2015. Please do not hesitate to contact me in case of any questions or concerns (416-667-2066).

Kind regards,

Krissy

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