

From: Krissy.Carrington@sanofipasteur.com
To: [Chattopadhyay, Rana](mailto:Chattopadhyay_Rana)
Cc: [Hoffman, Kelsy](mailto:Hoffman_Kelsy); [Rivers, Katie](mailto:Rivers_Katie); Dana.Harrison@sanofipasteur.com
Subject: RE: Additional information regarding the (b) (4)
Date: Tuesday, July 07, 2015 10:49:15 AM

Hi Rana

As requested, PR51 (b) (4) Lot (b) (4) PRN Immunogenicity (Mouse) results are provided in the below table.

(b) (4)

The event is recorded in the company's Quality notification system and is currently under investigation. Kind regards,
Krissy

From: Chattopadhyay, Rana [mailto:Rana.Chattopadhyay@fda.hhs.gov]
Sent: Thursday, July 02, 2015 3:13 PM
To: Harrison, Dana (sanofi pasteur)
Cc: Carrington, Krissy (sanofi pasteur); Hoffman, Kelsy; Rivers, Katie; Harrison, Dana (sanofi pasteur)
Subject: Re: Additional information regarding the (b) (4)

That should be fine, Ms. Harrison.

Rana

From: Dana.Harrison@sanofipasteur.com
Sent: Thursday, July 2, 2015 2:52 PM
To: Chattopadhyay, Rana
Cc: Krissy.Carrington@sanofipasteur.com; Hoffman, Kelsy; Rivers, Katie;
Dana.Harrison@sanofipasteur.com
Subject: RE: Additional information regarding the (b) (4)

Dear Mr. Chattopadhyay,

I acknowledge receipt of this additional request for information. Please note that, as our office is closed tomorrow (03 July 2015), it is unlikely that I will have a response before 06 July 2015.

Kind Regards,
Dana

From: Chattopadhyay, Rana [mailto:Rana.Chattopadhyay@fda.hhs.gov]
Sent: Thursday, July 02, 2015 2:02 PM
To: Harrison, Dana (sanofi pasteur)

Cc: Carrington, Krissy (sanofi pasteur); Hoffman, Kelsy; Rivers, Katie
Subject: Re: Additional information regarding the (b) (4)

Dear Ms. Harrison

Thank you, for the information. Can you please submit the result of PRN test for our review? You may send it through e-mail to us.

Thanks.

Rana

From: Dana.Harrison@sanofipasteur.com
Sent: Thursday, July 2, 2015 1:37 PM
To: Chattopadhyay, Rana
Cc: Hoffman, Kelsy; Rivers, Katie; Krissy.Carrington@sanofipasteur.com;
Dana.Harrison@sanofipasteur.com
Subject: RE: Additional information regarding the (b) (4)

Dear Mr. Chattopadhyay,

(b) (4) lot (b) (4) had an OOS result for the PRN Immunogenicity (Mouse) test. We confirm that (b) (4) lot (b) (4) is a launch lot.

Kind Regards,
Dana

Dana Harrison, MA
Manager, Regulatory Affairs
Sanofi Pasteur Limited
Phone: 416-667-2068
Cell: 416-358-2060
email: dana.harrison@sanofipasteur.com

From: Chattopadhyay, Rana [<mailto:Rana.Chattopadhyay@fda.hhs.gov>]
Sent: Wednesday, July 01, 2015 4:27 PM
To: Harrison, Dana (sanofi pasteur)
Cc: Hoffman, Kelsy; Rivers, Katie; Carrington, Krissy (sanofi pasteur)
Subject: RE: Additional information regarding the (b) (4)

Ms. Harrison

Please provide us with the information which test for PRN had the OOS for (b) (4) lot (b) (4). Also, please confirm if (b) (4) lot (b) (4) is a launch lot. You may please send these information through e-mail to us at your earliest, preferably by tomorrow, July 02, 2015.

Regards.

Rana

Rana Chattopadhyay, PhD

Biologist [Regulatory]
Division of Vaccines & Related Product Applications
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
US Food & Drug Administration
Room No. 3054, Building 71
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002.
Tel: 301-796-2640; Fax: 301-595-1244
E. Mail: rana.chattopadhyay@fda.hhs.gov

From: Dana.Harrison@sanofipasteur.com [<mailto:Dana.Harrison@sanofipasteur.com>]
Sent: Wednesday, July 01, 2015 1:48 PM
To: Chattopadhyay, Rana
Cc: Hoffman, Kelsy; Rivers, Katie; Krissy.Carrington@sanofipasteur.com;
Dana.Harrison@sanofipasteur.com
Subject: RE: Additional information regarding the (b) (4)

Dear Mr. Chattopadhyay,

Please see below responses to your request for information regarding (b) (4) lot (b) (4)

- 1) Lot (b) (4) was manufactured as a launch lot.
- 2) Lot (b) (4) was manufactured at commercial scale.
- 3) Lot (b) (4) had an out of specification for PRN, the result of which is currently under investigation. All other testing met the proposed specifications submitted as part of the BLA.

Kind Regards,

Dana

Dana Harrison, MA
Manager, Regulatory Affairs
Sanofi Pasteur Limited
Phone: 416-667-2068
Cell: 416-358-2060
email: dana.harrison@sanofipasteur.com

From: Chattopadhyay, Rana [<mailto:Rana.Chattopadhyay@fda.hhs.gov>]
Sent: Wednesday, July 01, 2015 9:27 AM
To: Harrison, Dana (sanofi pasteur)
Cc: Hoffman, Kelsy; Rivers, Katie; Carrington, Krissy (sanofi pasteur)
Subject: RE: Additional information regarding the (b) (4)
Importance: High

Dear Ms. Harrison

We need the following information regarding lot (b) (4) of (b) (4) as soon as possible, preferably by noon today-

- 1) What was the purpose of manufacturing this lot?
- 2) At what scale this lot was manufactured?
- 3) Did this lot pass all other testing apart from (b) (4) testing?

Regards.

Rana

Rana Chattopadhyay, PhD

Biologist [Regulatory]

Division of Vaccines & Related Product Applications

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

US Food & Drug Administration

Room No. 3054, Building 71

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002.

Tel: 301-796-2640; Fax: 301-595-1244

E. Mail: rana.chattopadhyay@fda.hhs.gov

From: Dana.Harrison@sanofipasteur.com [<mailto:Dana.Harrison@sanofipasteur.com>]

Sent: Tuesday, June 30, 2015 4:19 PM

To: Hoffman, Kelsy

Cc: Krissy.Carrington@sanofipasteur.com; Rivers, Katie; Chattopadhyay, Rana;

Dana.Harrison@sanofipasteur.com

Subject: RE: Additional information regarding the (b) (4)

Dear Ms. Hoffman,

I have received confirmation from my colleagues that there is one commercial scale lot currently available, lot number (b) (4) manufactured (b) (4) .

Kind Regards,

Dana

From: Hoffman, Kelsy [<mailto:Kelsy.Hoffman@fda.hhs.gov>]

Sent: Monday, June 29, 2015 10:33 AM

To: Harrison, Dana (sanofi pasteur)

Cc: Carrington, Krissy (sanofi pasteur); Rivers, Katie; Chattopadhyay, Rana

Subject: RE: Additional information regarding the (b) (4)

Ms. Harrison,

Please respond to this Information Request dated Friday, June 26, 2015, regarding the number of commercial scale lots currently available (with dates of manufacture and lot numbers) by no later than Wednesday, July 1, 2015.

Thank you,

Kelsy

Kelsy F. Hoffman, Ph.D.

LCDR, USPHS

Primary Reviewer/Regulatory Project Manager

FDA/CBER/OVRR/DVRPA

10903 New Hampshire Ave.

WO71-3205

Silver Spring, MD 20993-0002

Office- 301-796-2640
Fax- 301-595-1124

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

From: Hoffman, Kelsy
Sent: Friday, June 26, 2015 3:12 PM
To: 'Dana.Harrison@sanofipasteur.com'
Subject: RE: Additional information regarding the (b) (4)

Ms. Harrison,

Can you project a more specific date as to when you will submit this information? With regard to context, this requested information is necessary for our review of your submission.

Thanks,
Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
Primary Reviewer/Regulatory Project Manager
FDA/CBER/OVRR/DVRPA
10903 New Hampshire Ave.
WO71-3205
Silver Spring, MD 20993-0002
Office- 301-796-2640
Fax- 301-595-1124

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

From: Dana.Harrison@sanofipasteur.com [<mailto:Dana.Harrison@sanofipasteur.com>]
Sent: Friday, June 26, 2015 2:53 PM
To: Hoffman, Kelsy
Cc: Dana.Harrison@sanofipasteur.com
Subject: RE: Additional information regarding the (b) (4)

Dear Ms. Hoffman,

Following our telephone conversation, I have reached out to my colleagues to obtain the requested information (i.e., number of commercial scale lots currently available, dates of manufacture, and lot numbers). I will get this information to you as soon as possible next week. Could you please

provide the context for the request? Thanks.

Kind Regards,
Dana

Dana Harrison, MA
Manager, Regulatory Affairs
Sanofi Pasteur Limited
Phone: 416-667-2068
Cell: 416-358-2060
email: dana.harrison@sanofipasteur.com

From: Hoffman, Kelsy [<mailto:Kelsy.Hoffman@fda.hhs.gov>]
Sent: Friday, June 26, 2015 1:16 PM
To: Harrison, Dana (sanofi pasteur)
Subject: RE: Additional information regarding the (b) (4)

Ms. Harrison,

Please call me at 301-796-2640 as soon as possible.

Thanks,
Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
Primary Reviewer/Regulatory Project Manager
FDA/CBER/OVRR/DVRPA
10903 New Hampshire Ave.
WO71-3205
Silver Spring, MD 20993-0002
Office- 301-796-2640
Fax- 301-595-1124

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

From: Dana.Harrison@sanofipasteur.com [<mailto:Dana.Harrison@sanofipasteur.com>]
Sent: Thursday, June 25, 2015 1:43 PM
To: Rivers, Katie
Cc: Hoffman, Kelsy; Chattopadhyay, Rana; Krissy.Carrington@sanofipasteur.com;
Dana.Harrison@sanofipasteur.com
Subject: RE: Additional information regarding the (b) (4)

Dear Katie,

As stated during the Late Cycle Meeting (May 5, 2015) for STN125563/0, Sanofi Pasteur is providing

additional information regarding the investigation of the (b) (4)
Attached are 1.11.1 Quality Information Amendment, revised 3.2.P.5.6 Justification of Specifications, and Q_0544833 Report on Assessment of the Impact of Animal Weight and Breeding Location on the (b) (4) Test. These documents will also be submitted in an official BLA sequence later today.

Please confirm receipt of this documentation and feel free to contact me if you have any questions.

Kind Regards,
Dana

Dana Harrison, MA
Manager, Regulatory Affairs
Sanofi Pasteur Limited
Phone: 416-667-2068
Cell: 416-358-2060
email: dana.harrison@sanofipasteur.com

From: Rivers, Katie [<mailto:Katie.Rivers@fda.hhs.gov>]
Sent: Thursday, June 25, 2015 8:02 AM
To: Carrington, Krissy (sanofi pasteur)
Cc: Hoffman, Kelsy; Chattopadhyay, Rana; Harrison, Dana (sanofi pasteur)
Subject: RE: Additional information regarding the (b) (4)

Good Morning Krissy,

Thank you for letting us know, we'll look forward to receiving your submission today.

Katie

From: Krissy.Carrington@sanofipasteur.com [<mailto:Krissy.Carrington@sanofipasteur.com>]
Sent: Wednesday, June 24, 2015 4:03 PM
To: Rivers, Katie
Cc: Hoffman, Kelsy; Chattopadhyay, Rana; Dana.Harrison@sanofipasteur.com
Subject: RE: Additional information regarding the (b) (4)
Importance: High

File Ref No. STN BL 125563 PR5I (DTaP-IPV-Hib-HepB), (b) (4)

Dear Katie,

We are on track to provide the completed investigation report on Thurs 25 Jun 2015. We will send the information via email and official e-sequence via CBER ESG tomorrow.

Please note, I will be out of office with limited access to voicemail and email 25 Jun -03 Jul 2015 inclusive. Also, next Fri 03 Jul 2015 is CA/US statutory holiday and the Sanofi Pasteur CA/US sites are closed on this day.

For this timeframe please contact Dana Harrison, Regulatory Manager at 416-667-2068. Her email address is danaharrison@sanofipasteur.com. If CBER has any questions or concerns or would like to speak to any subject matter expert regarding this information during this timeframe, please do not hesitate to contact Dana to arrange this discussion. I appreciate it if you can cc: me on the correspondence during this timeframe. The 3 outstanding IR letters for the file (data exclusivity, CMC, LRP) responses are actively being addressed and I will provide you an update on targeted response dates when I'm back in the office, 06 Jul 2015. Thank you,
Krissy

From: Rivers, Katie [<mailto:Katie.Rivers@fda.hhs.gov>]
Sent: Friday, June 05, 2015 2:13 PM
To: Carrington, Krissy (sanofi pasteur)
Cc: Hoffman, Kelsy; Chattopadhyay, Rana
Subject: Additional information regarding the (b) (4)

Dear Ms. Carrington,

As stated during the Late Cycle Meeting (May 5, 2015) for STN125563/0, you will provide additional information regarding the ongoing investigation of the (b) (4) by the end of June. Please submit this information as an amendment to your BLA no later than June 25, 2015 to allow CBER sufficient time for review.

Thank you,
Katie

Katie H. Rivers, M.S.
Regulatory Project Manager, RRB1
FDA/CBER/OVRR/DVRPA
10903 New Hampshire Ave., HFM-481
Silver Spring, MD 20993-0002

Phone 301-796-2640
Fax 301-595-1244

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avertir l'expéditeur par retour de ce courriel, et supprimer la communication de

votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avvertir l'expéditeur par retour de ce courriel, et supprimer la communication de votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avvertir l'expéditeur par retour de ce courriel, et supprimer la communication de votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avvertir l'expéditeur par retour de ce courriel, et supprimer la communication de votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avvertir l'expéditeur par retour de ce courriel, et supprimer la communication de votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avvertir l'expéditeur par retour de ce courriel, et supprimer la communication de votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly

prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avvertir l'expéditeur par retour de ce courriel, et supprimer la communication de votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).

This communication and any attachments hereto may contain information that is confidential, proprietary or not intended for disclosure. If you are not the intended recipient, please note that any review, dissemination, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer. To unsubscribe from our electronic mailing list, [click here](#).

Cette communication ainsi que tout document joint aux présentes peut contenir des renseignements protégés par des droits, confidentiels ou soustraits à la divulgation en vertu de la loi. Si vous n'êtes pas le destinataire prévu, veuillez prendre note que la révision, la divulgation, la distribution ou la reproduction de cette communication sont strictement interdites. Si vous avez reçu cette communication par erreur, veuillez immédiatement en avvertir l'expéditeur par retour de ce courriel, et supprimer la communication de votre ordinateur. Pour retirer vos coordonnées de notre liste d'envoi électronique, [cliquer ici](#).