

From: Krissy.Carrington@sanofipasteur.com
To: [Rivers, Katie](#)
Cc: [Chattopadhyay, Rana](#); [Hoffman, Kelsy](#)
Subject: RE: Telecon Request - STN125563/0
Date: Monday, July 27, 2015 2:32:19 PM

Thanks very much for this confirmation. Kind regards,
Krissy

From: Rivers, Katie [mailto:Katie.Rivers@fda.hhs.gov]
Sent: Monday, July 27, 2015 2:18 PM
To: Carrington, Krissy (sanofi pasteur)
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: RE: Telecon Request - STN125563/0

Dear Ms. Carrington,

We have the following comment in follow-up to the July 24, 2015 teleconference:

We have considered your request (made during the July 24, 2015 teleconference) to re-evaluate our current thinking regarding the time point in the stability testing of (b) (4) at which the death of (b) (4) mice specification for (b) (4) may be applied. Please note that after further consideration within CBER, we advise you to use a specification of the death of (b) (4) mice for all stability time points. The specification for release will be the death of (b) (4) mice.

Please let me know if you have any questions.

Thank you,
Katie

From: Rivers, Katie
Sent: Monday, July 27, 2015 11:23 AM
To: 'Krissy.Carrington@sanofipasteur.com'
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: RE: Telecon Request - STN125563/0

Thank you Ms. Carrington,

The list of CBER attendees for the July 24, 2015 telecon is below:

Juan Arciniega, Ph.D.	DBPAP/OVRR
Drusilla Burns, Ph.D.	DBPAP/OVRR
Rana Chattopadhyay, Ph.D.	DVRPA/OVRR
Kelsy Hoffman, Ph.D.	DVRPA/OVRR
Katie Rivers, M.S.	DVRPA/OVRR
Michael Schmitt, Ph.D.	DBPAP/OVRR

Thank you,

Katie

From: Krissy.Carrington@sanofipasteur.com [<mailto:Krissy.Carrington@sanofipasteur.com>]
Sent: Friday, July 24, 2015 3:29 PM
To: Rivers, Katie
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: RE: Telecon Request - STN125563/0

Dear Katie,

Please find below the list of the participants for the 24 Jul 2015 CBER and MCM Vaccine Co. teleconference call regarding the Pertussis (b) (4) . I have highlighted the key speakers from our Analytical team for your reference.

Sanofi Pasteur List of Participants representing for MCM Vaccine Co.:

Erin Keyes, Deputy Director, IO/Manufacturing Technology

Jennifer Bucaille, Manager, QC Stability

Jean Yang, QC BioResources

(b) (4) , Scientist/Consultant, Analytical Process & Technology

Sophia Lee, Manager, Biostatistics, Quality Operations

Juthika Menon, Senior Scientist, Analytical Process & Technology

Meg Gao, Deputy Director, Modeling Process Control Strategy, Manufacturing Technology

Susan Nelson, Director, Analytical Process & Technology

Trevor Aldridge, Compliance Expert, Quality Operations

Maureen Barbalinardo, Deputy Director, RA CMC Conformance

Krissy Carrington, Deputy Director, Regulatory Affairs

Ellen Snell, Deputy Director, R&D Project Management

William Flounders, Senior Director, Project Leadership

Kind regards,

Krissy

From: Rivers, Katie [<mailto:Katie.Rivers@fda.hhs.gov>]
Sent: Thursday, July 16, 2015 8:26 AM
To: Carrington, Krissy (sanofi pasteur)
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: RE: Telecon Request - STN125563/0

Good Morning Ms. Carrington,

We will plan to use the call-in information you've provided below.

Yes, we would like to request repeat testing of (b) (4) using (b) (4) mice.

Please let me know if you have any additional questions.

Thank you,

Katie

From: Krissy.Carrington@sanofipasteur.com [<mailto:Krissy.Carrington@sanofipasteur.com>]
Sent: Wednesday, July 15, 2015 5:42 PM
To: Rivers, Katie
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: RE: Telecon Request - STN125563/0

Dear Katie

Thank you for the information below. I confirm we are available for a teleconference on Friday 24 Jul 2014 at 2PM. Please let me know if you will provide the dial-in no.s or we can use my dial-in.nos if that is convenient for you listed below for reference.

One of the points we will discuss is regarding item no. 2 listed below. For the CBER request, "Retest (b) (4) which have been continuously stored at 2-8 °C degrees, for (b) (4) using (b) (4) mice", we would like to highlight one set of results meeting this criteria is presented in the response to questions (STN 125563, Sequence 0012, 25 Jun 2015, Section 1.11.1 Quality Information Amendment page 23, Table 5). Could you please confirm that CBER would like this repeated? Thank you for your confirmation. Kind regards,
Krissy

Dial-In No.s:

North America: 1-877-304-0063

International Participants (other countries), click here <<http://www.intercall.com/sanofi-aventis/numbers/index.htm>> (If using mobile toll applies)

Conference code: (b) (4)

Leader PIN: (Krissy)

From: Rivers, Katie [<mailto:Katie.Rivers@fda.hhs.gov>]
Sent: Wednesday, July 15, 2015 12:19 PM
To: Carrington, Krissy (sanofi pasteur)
Cc: Chattopadhyay, Rana; Hoffman, Kelsy
Subject: RE: Telecon Request - STN125563/0

Hello Ms. Carrington,

The information provided below is what we plan on discussing during the telecon. Please let me know if Friday, July 24th at 2pm is acceptable.

Thank you,
Katie

The following testing activities should be completed to support the contention that (b) (4) is back in control:

1. Retest bulk lots (b) (4) mice.
2. Retest (b) (4), which have been continuously

stored at 2-8 °C degrees, for (b) (4) using (b) (4) mice. If sufficient samples are not available for such testing, please suggest an alternative.

The following is our current thinking concerning pending issues on the (b) (4) testing of (b) (4)

1. The release specification will be (b) (4) mice and the stability specification will be (b) (4) mice (beginning at 12 months); changes to these specifications may be considered if new, convincing information (e.g., effect of (b) (4) matrix on (b) (4) negative control test results) is submitted to CBER at some time in the future. Even if such data were immediately available for submission, we do not believe that sufficient time remains for adequate review of such data before the action due date for this file.
2. The dating period will be no more than 36 months; a longer dating may be considered as additional real-time data are accrued and submitted to CBER for review in the future.
3. (b) (4) commercial scale lots 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 would be evaluated and the decision to test only one lot per year on the stability program may be made in consultation with CBER.

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