

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125510/0.0
Review Office	OVRR
Applicant	Novartis Vaccines and Diagnostics, Inc. / Lic. # 1751
Product	Influenza Vaccine, Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	30-SEP-2015 10:05 AM
Author	GARNETT, THEODORE
Outside Phone Number	N/A – sent to the applicant by e-mail
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Request for a bioburden test template along with specifications and results to be included on the lot release protocol template
FDA Participants	LCDR Theodore Garnett
Applicant Participants	Mayuresh Gadre

Telecon Body:

From: Garnett, Theodore

Sent: Wednesday, September 30, 2015 10:05 AM

To: 'GADRE, MAYURESH'

Subject: RE: STN 125510/0 (FLUAD): Request for information

Dear Mayuresh,

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In response to NVD's comments and response provided in Amendment 23 (received by CBER on 29-SEPT-2015), we have the following additional information request:

Regarding 1.11.4 Information Amendment, page 21: Response to comment 1: “Please note that the bioburden test is not performed on (b) (4); the test is performed at (b) (4) manufacturing process (b) (4)”

A validation study was provided in amendment 125510/0.7 for bioburden testing performed on (b) (4) at the (b) (4) facility after receipt from (b) (4)

- Please include a bioburden test template along with specifications and results on the lot release protocol template for this testing conducted at (b) (4) prior to the (b) (4) (b) (4), and include the specifications in section 3.2.S.4.1.

Please provide this information in an amendment to the BLA. Feel free to contact me if you have any questions.

Regards,
Ted

From: GADRE, MAYURESH [<mailto:mayuresh.gadre@novartis.com>]
Sent: Monday, September 28, 2015 12:49 PM
To: Garnett, Theodore
Subject: RE: STN 125510/0 (FLUAD): Request for information

Dear Ted,

Please find attached the response document to information requests dated 18 Sept2015 and 24Sept2015. Also attached is Attachment 1 to 1.11.4 (EU PSUR 37 Appendix 2), updated Section 3.2.P.5.1 and Section 3.2.P.5.1 - Attachment 1 (Draft Lot Release Protocol template).

The target submission date for these responses is September 29, 2015. Please let me know if you have any questions.

Best Regards,
Mayuresh

Mayuresh Gadre
Senior Regulatory Affairs Specialist,
Regulatory Affairs North America
Novartis Vaccines and Diagnostics, Inc.
Phone: 617-871-8384
Email: mayuresh.gadre@novartis.com

From: Garnett, Theodore [<mailto:Theodore.Garnett@fda.hhs.gov>]
Sent: Friday, September 25, 2015 11:55 AM
To: GADRE, MAYURESH
Subject: RE: STN 125510/0 (FLUAD): Request for information

Sure. Thank you!

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Ted

From: GADRE, MAYURESH [<mailto:mayuresh.gadre@novartis.com>]
Sent: Friday, September 25, 2015 11:47 AM
To: Garnett, Theodore
Subject: RE: STN 125510/0 (FLUAD): Request for information

Dear Ted,

The responses to the information request dated 18 September and the information request received yesterday will be submitted Monday or Tuesday next week. Would you also like to receive the response by email as soon as it is available?

Best Regards,
Mayuresh

Mayuresh Gadre
Senior Regulatory Affairs Specialist,
Regulatory Affairs North America
Novartis Vaccines and Diagnostics, Inc.
Phone: 617-871-8384
Email: mayuresh.gadre@novartis.com

From: Garnett, Theodore [<mailto:Theodore.Garnett@fda.hhs.gov>]
Sent: Friday, September 18, 2015 3:02 PM
To: GADRE, MAYURESH
Subject: STN 125510/0 (FLUAD): Request for information

Dear Mayuresh,

Please find attached a new request for information from CBER. Please respond by September 25th, if possible.

Best regards,

Ted

Theodore Garnett, Ph.D.
LCDR, U.S. Public Health Service
Microbiologist (Regulatory)
U.S. Food and Drug Administration
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U.S. Public Health Service Rapid Deployment Force PHS-2 ("*Second to None*") Admin/Finance
Section, Home Support Branch Director

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