

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	08-OCT-2015 09:54 AM
Author	GARNETT, THEODORE
Outside Phone Number	N/A – Request sent by e-mail
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Request for information regarding the (b) (4) test range
FDA Participants	Theodore Garnett Brenda Baldwin
Applicant Participants	Mayuresh Gadre

Telecon Body:

From: Garnett, Theodore

Sent: Thursday, October 08, 2015 9:54 AM

To: 'GADRE, MAYURESH'

Cc: Baldwin, Brenda

Subject: STN 125510/0 (FLUAD 65): Request for information regarding the (b) (4) test range

Dear Mr. Gadre,

We have noticed an inconsistency in the acceptance range for the (b) (4) test for (b) (4) preparation. Specifically the Manufacturing-process-and-controls Table

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3.2.P.3.3.3-1 and Control-critical-steps Table 3.2.P.3.4-3/ Table 3.2.P.3.4-5 (b) (4) differ from the Process validation Table 3.2.P.3.5.5.1-2 and attachment 5 page 21 document (b) (4). Please clarify if this is a typographical error. If it is, please correct the appropriate tables and/or documents and submit as an amendment to the BLA by Friday, October 9, 2015, if possible. If it is not an error, please explain.

Regards,

Theodore Garnett, Ph.D.

LCDR, U.S. Public Health Service

Microbiologist (Regulatory)

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