

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	15-OCT-2015 12:18 PM
Author	GARNETT, THEODORE
Outside Phone Number	N/A – Request sent by e-mail
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Question regarding the location of changes to the DS section for the antigen
FDA Participants	Theodore Garnett Brenda Baldwin
Applicant Participants	Mayuresh Gadre

Telecon Body:

From: Garnett, Theodore
Sent: Thursday, October 15, 2015 12:18 PM
To: 'GADRE, MAYURESH'
Cc: Baldwin, Brenda
Subject: STN 125510 (FLUAD): Information Request

Dear Mr. Gadre,

We have reviewed amendment 24 to your original BLA (STN 125510) and have been unable to locate two of the indicated changes to the Drug Substance section for the antigen. Please point out where these changes are located or submit the updated DS section to the BLA for 1) the

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(b) (4)

If possible, please respond by Monday, October 19, 2015.

Regards,

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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