

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

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

## Telecon Details

<b>Telecon Date/Time</b>	24-SEP-2015 07:24 AM
<b>Author</b>	GARNETT, THEODORE
<b>Outside Phone Number</b>	N/A – sent to the applicant by e-mail
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Requests regarding the lot release protocol template
<b>FDA Participants</b>	LCDR Theodore Garnett
<b>Applicant Participants</b>	Mayuresh Gadre

### Telecon Body:

**From:** Garnett, Theodore

**Sent:** Thursday, September 24, 2015 7:24 AM

**To:** 'GADRE, MAYURESH'

**Subject:** STN 125510 (FLUAD): IR regarding LRP template

Dear Mr. Gadre,

Regarding the lot release protocol template:

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- On pages 6, 10 and 14 (test data for (b) (4)) a Sterility test template is provided. This should be replaced with a Bioburden test template, including respective test details and specifications, or using CBER Bioburden template (attached).
- On pages 7, 11 and 14, the specification for the (b) (4) Test shows a specification of (b) (4). In amendment 125510/0/7, the specification is shown as (b) (4). Please correct in the LRP template.
- In section 3.2.S.4.1 (Specification for (b) (4)) the specification for Bioburden and Endotoxin should also be updated.

Please submit these changes as an amendment to your BLA.

Regards,

Theodore Garnett, Ph.D.

LCDR, U.S. Public Health Service

Microbiologist (Regulatory)

U.S. Food and Drug Administration

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