

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125510/0
<b>Review Office</b>	OVR
<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>	01-Oct-2015 3:58 PM
<b>Author</b>	GARNETT, THEODORE
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Questions regarding NVD's response to IR dated 9/18/15 and requests made during the Late-Cycle Communication meeting
<b>FDA Participants</b>	LCDR Theodore Garnett
<b>Applicant Participants</b>	Mayuresh Gadre

### Telecon Body:

**From:** Garnett, Theodore  
**Sent:** Thursday, October 01, 2015 3:58 PM  
**To:** 'GADRE, MAYURESH'  
**Subject:** STN 125510/0 (FLUAD): Request for information

Dear Mayuresh,

Please find attached a new request for information from CBER. Let me know if you have any questions.

Best regards,

Ted

Theodore Garnett, Ph.D.  
LCDR, U.S. Public Health Service  
Microbiologist (Regulatory)  
U.S. Food and Drug Administration  
CBER|OVR|DVRPA|CMC3  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

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Office: 301-796-2640

Cell: (b) (6)

U.S. Public Health Service Rapid Deployment Force PHS-2 (*"Second to None"*) Admin/Finance  
Section, Home Support Branch Director

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring, MD 20993-0002

DATE: October 1, 2015

TO: Mayuresh Gadre, M.S.

FROM: LCDR Theodore Garnett, Ph.D.  
CBER/OVRR/DVRPA

SUBJECT: BLA 125510/0

PRODUCT: FLUAD

SPONSOR: Novartis Vaccines and Diagnostics

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We are reviewing your biologics license application (BLA) dated November 25, 2014, for Influenza Vaccine, Adjuvanted and have the following additional requests:

1. Regarding your responses to our pharmacovigilance questions in the information request dated September 18, 2015:
  - a. We understand that you are waiting for the preliminary assessment report by the Reference Member State, which is due at the beginning of October, before you can amend the Risk Management Plan. Please provide the Risk Management Plan version 4.0 to us when this procedure is closed.
  - b. To clarify the issue of Adverse Events of Special Interest (AESIs):
    - i. Please provide summaries of AESIs in the period (quarterly) reports, as required under 21 CFR§600.80(c)(2), using the same list of conditions as described in the section "AEs of Special Interest (AESIs)" on pages 33-34 of PSUR 37.
    - ii. Additionally, please provide expedited reports of the following conditions as previously communicated (Guillain Barré Syndrome, ITP, Neuritis, Encephalomyelitis, Vasculitis, Demyelination, Bell's palsy) and described in 21 CFR§600.80(c)(1)(i).
  - c. Thank you for providing the EU Regional Appendices. Please clarify whether the third party sponsored (i.e. investigator initiated) active surveillance in the Lazio region in Italy (study V70\_58OBTP in the previous season) is the same as the active surveillance study in Italy following the

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proof-of-concept protocol received from Dr. Salmaso of the Istituto Superiore di Sanità (ISS) on June 27, 2014.

2. As discussed in the late-cycle communication meeting, please submit the tech transfer and bridging data including the master transfer plan for the change of the release testing location from (b) (4) as an amendment to STN 125510 by NLT October 7, 2015.
3. As discussed in the late-cycle communication meeting, please submit the Agriflu manufacturing changes submitted to and approved under STN 125197 as an amendment to STN 125510 by NLT October 7, 2015. Please also indicate if the Fluad lots received by CBER on September 3, 2015, for in-support testing were manufactured with these changes.

Please submit the requested information as an amendment to your BLA. We recommend that you restate each item and follow it with your response. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference.

If you have any questions, please contact the Regulatory Project Manager, LCDR Theodore Garnett, Ph.D., at (301) 796-2640.