

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125510/0 Office: OVRR

Product:  
Influenza Vaccine, Adjuvanted

Applicant:  
Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 07-August-2015 4:20 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):  
1. Information Request

Author: Theodore Garnett

Telecon Summary:  
CBER request for a description of alternative plans for safety surveillance

FDA Participants: Theodore Garnett

Non-FDA Participants: Mayuresh Gadre

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

**From:** Garnett, Theodore  
**Sent:** Friday, August 07, 2015 4:20 PM  
**To:** 'GADRE, MAYURESH'  
**Subject:** STN 125510/0 (FLUAD): Request for information

Dear Mayuresh,

Please find attached a new request for information from CBER. Feel free to contact me if you have any questions or concerns.

Best regards,

Ted

**Theodore Garnett, Ph.D.**

LCDR, U.S. Public Health Service

Microbiologist (Regulatory)

U.S. Food and Drug Administration

CBER|OVRP|DVRPA|CMC3

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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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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring, MD 20993-0002

DATE: August 7, 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 request for additional information. Please promptly submit your response to the following item so that we may continue evaluating your BLA:

Reference is made to Amendment 14 in which you provide a partial response to our information request dated May 15, 2015:

According to the RMP/PVP, NVD originally expected approximately 150 to 200 participants above 65 years of age to be exposed to Fluad in the PCIRN during each season, including the 2014/2015 season. However, information from the final report of the PCIRN 2014 seasonal influenza safety surveillance (attachment 5) indicated that "Fluad was only given at 2 of our sites this year and the number who received it (n=51) and who completed the day 8 survey was very small (n=36) thus limiting the ability to detect signals in our sample."

During the 2014 season, there were 95 elderly subjects enrolled in the Italian study with Fluad exposure.

Please indicate if NVD has alternative plans to detect potential signals if the ability of PCIRN or the Italian study for signal detection is limited by the number of vaccinees captured by the system. If so, please provide a description of your plans.

Please submit the requested information as an amendment to the BLA as soon as possible. We recommend that you restate the comment 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.