

## 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: 09-January-2015 2:23 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):  
1. Information Request

Author: Theodore Garnett

Telecon Summary:  
Request regarding sample availability for CBER testing

FDA Participants: Theodore Garnett

Non-FDA Participants: Matthew Gollwitzer

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

**From:** Garnett, Theodore  
**Sent:** Friday, January 09, 2015 2:23 PM  
**To:** matthew.gollwitzer@novartis.com  
**Subject:** STN 125510/0 (FLUAD 65): Information Request

Hi Matt,

Attached is an information request from the review team. Please acknowledge receipt of this request.

Thanks,  
Ted

**Theodore Garnett, Ph.D.**

LCDR, U.S. Public Health Service

Microbiologist (Regulatory)

U.S. Food and Drug Administration

CBER|OVRP|DVRPA|CMC3

10903 New Hampshire Avenue

Silver Spring, MD 20993

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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**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
OFFICE OF VACCINES RESEARCH AND REVIEW  
DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS**

**Date:** January 9, 2015

**Pages:** 2

**To:** Matthew Gollwitzer  
Associate Director, Regulatory Affairs, North America  
Novartis Vaccines and Diagnostics, Inc.  
350 Massachusetts Avenue  
Cambridge, MA 02139  
Telephone: (617) 871-8325 Fax: (617) 871-4711

**From:** Division of Vaccines and Related Products Applications  
Office of Vaccines Research and Review  
Point of Contact: LCDR Theodore Garnett, Ph.D.  
Regulatory Project Manager  
10903 New Hampshire Ave., White Oak Bldg. 71  
Silver Spring, MD 2993-0002  
Telephone: (301) 796-2640 Fax: (301) 595-1124

**STN#:** 125510/0

**Product:** Influenza Vaccine (IV), adjuvanted

**Subject:** Samples available for testing during BLA process

Our review of your November 25, 2014 submission (STN 125510/0) is ongoing. We have the following request for additional information:

*Please clarify what samples will be available to be sent to CBER for testing during the BLA process. Please also confirm that lots for final release will be submitted as final bulk. We would be interested in receiving samples (both monovalent bulks and final bulk) by April 2015 for SRID potency testing, but other testing may also be conducted later in the review process.*

Please submit the requested information as an amendment to STN 125510/0. We recommend that you restate the 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 LCDR Theodore Garnett, Ph.D., at 301-796-2640.