

## 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: 16-January-2015 3:33 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):  
1. Information Request

Author: Theodore Garnett

Telecon Summary:  
Request for formal responses to IRs

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 16, 2015 3:33 PM  
**To:** 'Gollwitzer, Matthew'  
**Cc:** Baldwin, Brenda  
**Subject:** BLA 125510/0 (FLUAD 65): Request for formal submission of IRs

Hi Matt,

The attached memo contains (and references) information requests that we previously submitted via e-mail and/or telephone and to which you have provided unofficial responses. Please provide formal responses to these requests. We also submitted an IR on 1/9/15 to which you have not responded. Please provide a formal response to this IR at your earliest convenience.

Thank you,  
Ted

Theodore Garnett, Ph.D.  
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Microbiologist (Regulatory)  
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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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**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
OFFICE OF VACCINES RESEARCH AND REVIEW  
DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS**

**Date:** January 16, 2015

**Pages:** 2

**To:** Matthew Gollwitzer  
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**From:** Division of Vaccines and Related Products Applications  
Office of Vaccines Research and Review  
Point of Contact: LCDR Theodore Garnett, Ph.D.  
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**STN#:** 125510/0

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

**Subject:** Request for formal responses to IRs

Our review of your November 25, 2014 submission (STN 125510/0) is ongoing and, to date, we have made a number of requests for information via e-mail and telephone for which you have submitted unofficial responses. We would like to request formal responses to the IRs dated 12/9/14 and 12/17/14 and to the following questions:

1. Please provide the (b) (4) SOP for the HAI assay used in determining the titers in pivotal trial V70\_27. Additionally, please provide an illustration of the sera dilution and HAI test results calculations of the (b) (4) HAI assay SOP.
2. There were 3 ongoing PAS's for Agriflu outlined in Section 2.2 – Introduction.
  - a. Please provide the timelines for these submissions.
  - b. Please indicate whether these changes for Agriflu have already been implemented for FLUAD

If the answers to “b” is “yes”, have any of the clinical lots included in the BLA filing used any of the modified manufacturing processes?

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.