

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-December-2014 11:01 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 clinical investigator contact information

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: Tuesday, December 09, 2014 11:01 AM
To: 'matthew.gollwitzer@novartis.com'
Subject: STN 125510/0 (Influenza Vaccine, adjuvanted): IR for clinical investigator contact information

Dear Matthew,

I am one of the project managers for your original BLA submission STN 125510. I will be your primary contact at the FDA and will be forwarding information requests to you from the CBER review team. Attached is one such IR.

If you have any questions or concerns, please don't hesitate to contact me. I look forward to working with you.

Best regards,

Ted

P.S.: Please acknowledge receipt of this e-mail.

Theodore Garnett, Ph.D.

LCDR, U.S. Public Health Service

Microbiologist (Regulatory)

U.S. Food and Drug Administration

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

Date: December 9, 2014

Pages: 2

To: Matthew Gollwitzer
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From: Division of Vaccines and Related Products Applications
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Point of Contact: LCDR Theodore Garnett, Ph.D.
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Telephone: (301) 796-2640 Fax: (301) 595-1124

STN#: 125510/0

Product: Influenza Vaccine (IV), adjuvanted

Subject: CBER request for clinical investigator contact information

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

For each of the clinical studies listed in section 5.2 of the BLA, please furnish a list showing the name and address of each participating clinical investigator along with their telephone number and corresponding study site number.

Please submit the requested information as an amendment to STN 125510/0 as soon as possible. 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.

For this and all future submissions, please ensure that the U.S. license number for your firm is included in FDA Form 356h. If you have any questions, please contact LCDR Theodore Garnett, Ph.D., at 301-796-2640.