

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: 28-May-2015 10:57 AM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):
1. Information Request

Author: Theodore Garnett

Telecon Summary:
CBER comments regarding bioburden and sterility testing for the (b) (4)

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: Thursday, May 28, 2015 10:57 AM
To: 'GADRE, MAYURESH'
Subject: STN 125510/0 (FLUAD 65): 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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