

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: 17-March-2015 3:40 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):
1. Information Request

Author: Theodore Garnett

Telecon Summary:
Questions regarding the Ovalbumin assay

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: Tuesday, March 17, 2015 3:22 PM
To: 'GADRE, MAYURESH'
Subject: FLUAD 65 - New Information Request

Dear Mayuresh,

Attached is a new information request from the Review Team. Please acknowledge receipt of this request and provide a response at your earliest convenience so we may continue the timely review of your submission.

Thanks,
Ted

Theodore Garnett, Ph.D.

LCDR, U.S. Public Health Service

Microbiologist (Regulatory)

U.S. Food and Drug Administration

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