

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-April-2015 9:36 AM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):
1. Information Request

Author: Theodore Garnett

Telecon Summary:
CBER request for English translation of COAs and confirmation of post-licensure production parameters

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: Friday, April 17, 2015 9:36 AM
To: 'GADRE, MAYURESH'
Subject: RE: STN 125510 (FLUAD 65): New Information Resquest - SRID Assay

[Here's an additional request I received this morning.](#)

Thanks,
Ted