

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: 01-April-2015 12:15 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):
1. Information Request

Author: Theodore Garnett

Telecon Summary:
Request to correct HAI titers for pivotal trial V70_27

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: Wednesday, April 01, 2015 12:15 PM
To: 'GADRE, MAYURESH'
Subject: FLUAD 65 - New Information Request

Dear Mayuresh,

Attached is a new information request from the CBER Review Team regarding the HAI titers for pivotal trial V70_27. Please acknowledge receipt of this request and provide a response via an amendment to your BLA no later than May 4, 2015.

Thank you!

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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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

DATE: April 1, 2015

TO: Mayuresh Gadre, M.S.

FROM: LCDR Theodore Garnett, Ph.D.
CBER/OVRR/DVRPA

SUBJECT: BLA 125510/0

PRODUCT: FLUAD 65

SPONSOR: Novartis Vaccines and Diagnostics

We have reviewed your response dated March 16, 2015, to our February 18, 2015, request to correct your HAI titers for pivotal trial V70_27.

We do not agree that the reported HAI titers for pivotal trial V70_27 as determined using SOP.119.057 are correct, because the serum dilution definition under SOP.119.057 is not consistent with how serum dilution is traditionally defined by CBER in this assay. The comparability study (Document # REPT.119.00092-FDX) you provided is not applicable in this situation.

Because you are seeking approval under the accelerated approval pathway and possible licensure will be based solely on the immunogenicity data (and no efficacy data), the HAI results from the V70_27 pivotal trial will need to be re-calculated. We request that you re-calculate your titers based on the 1:5 initial serum dilution and include revised datasets as well as an updated version of the clinical study report as previously requested. Please provide this information in an amendment to your BLA by no later than May 4, 2015.

In your reply to this memo, we recommend that you restate our request 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 Dr. Theodore Garnett at 301-796-2640.