

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: 29-July-2015 2:39 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):

1. Information Request

Author: Theodore Garnett

Telecon Summary:

CBER request regarding the lot release template and SRID 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: Wednesday, July 29, 2015 2:39 PM

To: 'GADRE, MAYURESH'

Subject: STN 125510/0 (FLUAD): 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

10903 New Hampshire Avenue

Silver Spring, MD 20993

Office: 301-796-2640

Cell: (b) (6)

U.S. Public Health Service Rapid Deployment Force PHS-2 ("*Second to None*") Admin/Finance
Section, Home Support Branch Director

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone."



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

DATE: July 29, 2015

TO: Mayuresh Gadre, M.S.

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

SUBJECT: BLA 125510/0

PRODUCT: FLUAD

SPONSOR: Novartis Vaccines and Diagnostics

We are reviewing your biologics license application (BLA) dated November 25, 2014, for Influenza Vaccine, Adjuvanted and have the following comments and requests for additional information. Please promptly submit your response to the following items so that we may continue evaluating your BLA:

Lot Release Protocol Template submitted in amendment 15 (3.2.P.5.1) dated July 13, 2015:

1. Pages 5, 9, 13 and 17: On each table showing test and specification data, under the Specification column, please replace 'conforms' with the actual specification for the test.
2. Pages 6, 10 and 14 (Potency test of (b) (4)): The tables for the test data still contain a column with 'p value'. This is not validity criteria for the (b) (4) method of analysis; please remove this column.

SRID Assay

In reference to CBER comment 8.b (regarding design of SRID assay accuracy study), submitted in the information request dated May 15, 2015, you provided a response in amendment 15 (125510/0.15) submitted on July 13, 2015. We have an additional question regarding your response. You stated:

“The company confirms the agency’s interpretation of the accuracy study that has been performed. It had been adopted directly from the current approved methodology for determination of accuracy for non-adjuvanted vaccines. Virus reference standard supplied by CBER is reconstituted in water as per instructions supplied prior to being (b) (4) basis with a known potency of Product. A repeated study will be performed through reconstituting CBER Virus reference standard in a (b) (4) ratio to ensure the MF59 is at the correct Drug Product matrix concentration for assessment within an accuracy study. This study will be undertaken for all strains in 2015.”

3. Please provide the timeline when the results of the planned repeat accuracy study will be submitted. We recommend that these results be submitted as soon as possible so that review of potency assay can be completed.

Please submit the requested information as an amendment to the BLA as soon as possible. We recommend that you restate each 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.

If you have any questions, please contact the Regulatory Project Manager, LCDR Theodore Garnett, Ph.D., at (301) 796-2640.