

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125510/0
Review Office	OVRR
Applicant	Novartis Vaccines and Diagnostics, Inc. / Lic. # 1751
Product	Influenza Vaccine, Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	04-SEP-2015 2:28 PM
Author	GARNETT, THEODORE
FDA Originated?	Yes
Communication Categories	IR
Related STNs	None
Related PMCs	None
Telecon Summary	Request for enhanced surveillance and expedited reporting of AESIs and a revised Risk Management Plan
FDA Participants	Theodore Garnett Ramachandra Naik
Applicant Participants	Mayuresh Gadre

Telecon Body:

From: Garnett, Theodore

Sent: Friday, September 04, 2015 2:28 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|OVRR|DVRPA|CMC3
10903 New Hampshire Avenue
Silver Spring, MD 20993

RECORD OF TELEPHONE CONVERSATION

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."

RECORD OF TELEPHONE CONVERSATION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

DATE: September 4, 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 regarding your pharmacovigilance plan:

1. As follow-up to our discussion in the late-cycle communication meeting yesterday, at this time we would like enhanced surveillance performed and 15-day expedited reports provided to VAERS for the following AESIs:
 - Guillain Barre Syndrome
 - ITP
 - Neuritis
 - Encephalomyelitis
 - Vasculitis
 - Demyelination
 - Bell's palsy
2. Regarding your IR response received on September 3, 2015, please revise your Risk Management Plan to reflect the changes in surveillance as you have described. We request that the updated plan be submitted to the BLA by NLT Wednesday, September 9, 2015.

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.

RECORD OF TELEPHONE CONVERSATION

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