

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: 05-August-2015 2:34 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 to update latex statement language in the PI

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, August 05, 2015 2:34 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

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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: August 5, 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. Please promptly submit your response so we may continue evaluating your BLA:

The latex statement language on the prefilled syringe carton C10 and C18, and the package insert, is not consistent with CBER's December 2, 2014, Guidance, *Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not made with Natural Rubber Latex* (attached).

Please confirm that natural rubber latex was not used as a material in the tip caps and either remove the latex text language or use the following text to be consistent with recent FDA Guidance.

The tip caps of the prefilled syringes are not made with natural rubber latex.

Alternatively, if you are unable to confirm that natural rubber latex was not used as a material in the tip caps then the following text should be used.

The tip caps of the prefilled syringes contain natural rubber latex, which may cause allergic reactions in latex sensitive individuals.

Please update the drug product language in the Package Insert and the Syringe Cartons so that it is consistent with the guidance and submit the revised labels as an amendment to BLA 125510.

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