

## 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: 10-April-2015 2:47 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):  
1. Other

Author: Theodore Garnett

Telecon Summary: Response to clarification questions

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 10, 2015 2:47 PM  
**To:** 'GADRE, MAYURESH'  
**Subject:** RE: FLUAD 65 - New Information Request

Mayuresh,

Responses to your questions are attached. Feel free to contact me if you have any additional concerns.

Regards,  
Ted

**From:** GADRE, MAYURESH [<mailto:mayuresh.gadre@novartis.com>]  
**Sent:** Friday, April 03, 2015 2:28 PM  
**To:** Garnett, Theodore  
**Subject:** RE: FLUAD 65 - New Information Request

Dear Ted,

Novartis acknowledges the communication from CBER dated 01 April 2015 as it relates to the calculation of HI titers in study V70\_27. Novartis is rapidly organizing teams to respond to these requests but would like to clarify a few points to ensure CBER receives the information they need to continue with review of this file in a timely fashion.

- 1) Novartis proposes to recalculate the HAI titer values as measured in study V70\_27 by dividing the original value by (b) (4). Does CBER agree?
- 2) Novartis proposes to perform this adjustment in titer in the programmed analysis rather than directly in transforming (b) (4) data. Does CBER agree?
- 3) Does CBER agree the data may be provided in SDTM format?
- 4) CBER has requested an updated CSR. Novartis proposes to provide the data as two addenda CSRs. The first would be focused on the results of the reanalysis of the primary objectives. The second would be focused on the results of the reanalysis of the secondary objectives. Does CBER agree with this proposal?

Please note that upon confirmation of this information, Novartis will confirm the feasibility of submitting these responses by 4<sup>th</sup> May as requested by CBER. Your responses to these questions are greatly appreciated and the company will make its experts available for a call at short notice if CBER believe this is helpful.

Please let me know if you have any questions.

Best Regards,  
Mayuresh

Mayuresh Gadre  
Senior Regulatory Affairs Specialist,  
Regulatory Affairs North America  
Novartis Vaccines and Diagnostics, Inc.  
Phone: 617-871-8384  
Email: [mayuresh.gadre@novartis.com](mailto:mayuresh.gadre@novartis.com)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring, MD 20993-0002

DATE: April 10, 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 request for clarification dated April 03, 2015, in reference to our April 1, 2015, communication regarding correcting your HAI titers for pivotal trial V70\_27.

Below are CBER's responses (*Italics*) to your questions (**bolded**).

- 1) **Novartis proposes to recalculate the HAI titer values as measured in study V70\_27 by dividing the original value by (b) (4). Does CBER agree?**

*Yes, CBER agrees.*

- 2) **Novartis proposes to perform this adjustment in titer in the programmed analysis rather than directly in transforming (b) (4) data. Does CBER agree?**

*Yes, CBER agrees.*

- 3) **Does CBER agree the data may be provided in SDTM format?**

*Yes, CBER agrees.*

- 4) **CBER has requested an updated CSR. Novartis proposes to provide the data as two addenda CSRs. The first would be focused on the results of the reanalysis of the primary objectives. The second would be focused on the results of the reanalysis of the secondary objectives. Does CBER agree with this proposal?**

*CBER does not agree. We continue to request that you submit an updated CSR with all changes resulting from the recalculation of the HAI titers for V70\_27, including the results of the reanalysis of both the primary and secondary objectives. In addition,*

*please provide a clean and tracked changes version of the updated CSR. Please acknowledge.*

In your official response to our April 1, 2015, communication, please reference your April 3, 2015, request for clarification and include our response in the format above. 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.