

## 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: 21-July-2015 2:44 PM Initiated by FDA? N/A

Telephone Number: N/A – E-mail communication

Communication Category(ies):  
1. Other, Advice

Author: Theodore Garnett

Telecon Summary:  
CBER recommendation and Novartis response regarding the proposed proprietary names for (b) (4)

FDA Participants: Brenda Baldwin and Theodore Garnett

Non-FDA Participants: Mayuresh Gadre

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

**From:** GADRE, MAYURESH [mailto:mayuresh.gadre@novartis.com]

**Sent:** Tuesday, July 21, 2015 2:44 PM

**To:** Baldwin, Brenda

**Cc:** Garnett, Theodore

**Subject:** RE: BLA 125510/0 - amendment 12 (submitted 6-5-15)

Dear Brenda,

Reference is made to the email correspondence (below) dated July 1, 2015. Reference is also made to the "Request for Comments and Advice" with respect to proposed proprietary names for the trivalent (b) (4) formulations of Novartis adjuvanted seasonal influenza vaccines, submitted on June 5, 2015 to BLA 125510.

Below is the Novartis' response to CBER recommendation. CBER comment is reproduced below, in italics, with the Company response immediately following.

**FDA Comment:**

*We have reviewed your proposed proprietary names for the (b) (4) formulation of your adjuvanted seasonal influenza vaccine (Agriflu backbone). You have proposed two different names for the two different age groups. As you are aware, there should only be one proprietary name per formulation. The name should not be based on the indicated age group(s), as health care providers will be able to read the label and determine the correct dosage for each age group.*

*In addition, we have also expressed concern with the proposed proprietary name of FLUAD 65 for the trivalent formulation under review. Specifically the modifier '65' is problematic. At this time we request that you drop the '65' as it is deemed promotional. The proprietary name of FLUAD without a modifier will be acceptable.*

**Novartis Response:**

Novartis acknowledges the agencies comments and proposes the name FLUAD for the trivalent formulation (aTIV), to be marketed in the elderly age group only, which will later evolve into FLUAD (b) (4) upon approval of the (b) (4) formulation (b) (4) for market to both pediatric and elderly populations.

Novartis kindly requests confirmation of FDA alignment with the above outlined proposal.

Should this response also be submitted officially to the BLA?

Should you require further clarification, please feel free to contact me. Thank you.

Best Regards,  
Mayuresh

Mayuresh Gadre  
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Regulatory Affairs North America  
Novartis Vaccines and Diagnostics, Inc.  
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**From:** Baldwin, Brenda [<mailto:Brenda.Baldwin@fda.hhs.gov>]  
**Sent:** Wednesday, July 01, 2015 11:09 AM  
**To:** GADRE, MAYURESH  
**Cc:** Garnett, Theodore  
**Subject:** BLA 125510/0 - amendment 12 (submitted 6-5-15)

We have reviewed your proposed proprietary names for the (b) (4) formulation of your adjuvanted seasonal influenza vaccine (Agriflu backbone). You have proposed two different names for the two different age groups. As you are aware, there should only be one proprietary name per formulation. The name should not be based on the indicated age group(s), as

health care providers will be able to read the label and determine the correct dosage for each age group.

In addition, we have also expressed concern with the proposed proprietary name of FLUAD 65 for the trivalent formulation under review. Specifically the modifier '65' is problematic. At this time we request that you drop the '65' as it is deemed promotional. The proprietary name of FLUAD without a modifier will be acceptable.

Dr. Brenda R. Baldwin  
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