

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: 18-February-2015 10:47 AM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):
1. Other

Author: Brenda Baldwin

Telecon Summary:
Response to Proprietary Name Review request

FDA Participants: Brenda Baldwin

Non-FDA Participants: Matthew Gollwitzer

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Baldwin, Brenda [<mailto:Brenda.Baldwin@fda.hhs.gov>]

Sent: Wednesday, February 18, 2015 10:47 AM

To: Gollwitzer, Matthew

Subject: IND 14368/BLA 125510

Hi Matt,

Attached is our response to your Proprietary Name Review request submitted to IND 14368. When available, please provide the name(s) you intend to use for (b) (4) in the pediatric age group and (b) (4) in the elderly age group.

Regards,
Brenda

Dr. Brenda R. Baldwin
Food and Drug Administration/CBER/OVRR/DVRPA
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Our STN: BLA 125510/0 and IND 14368

Novartis Vaccines and Diagnostics, Inc.
Attention: Matthew Gollwitzer
350 Massachusetts Avenue
Cambridge, MA 02139

Dear Mr. Gollwitzer:

We have reviewed your submission dated August 22, 2014, to your IND 14368 for Influenza Vaccine, Adjuvanted, requesting a proprietary name review.

We have consulted with CBER's Advertising and Promotional Labeling Branch (APLB) which recommends that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, FLUAD 65, is acceptable at this time with concern. Our concern is there is a risk the modifier '65' may be problematic for future licensure of the same formulation in other age groups and/or it may be dropped by healthcare providers and patients and this could affect the nomenclature of future FLUAD formulations.

You may submit a new proprietary name for FDA consideration to your Biologics License Application (BLA 125510) for Influenza Vaccine, Adjuvanted. Any alternative proprietary name(s) should comply with the regulations regarding false, misleading or fanciful names and should not be confused with other medicinal products with orthographic or phonological similarities.

We will perform another proprietary name review of FLUAD 65 closer to the time of the action due date of BLA 125510 to ensure that we have not approved a conflicting proprietary name for another product in the interim.

If you have any questions, please contact Dr. Brenda Baldwin at (301) 796-2640.