

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125510/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Novartis Vaccines and Diagnostics, Inc. / Lic. # 1751
<b>Product</b>	Influenza Vaccine, Adjuvanted
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	29-OCT-2015 07:52 PM
<b>Author</b>	BALDWIN, BRENDA
<b>Outside Phone Number</b>	N/A – email correspondence
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Request for commitment to postmarketing requirements
<b>FDA Participants</b>	Brenda Baldwin
<b>Applicant Participants</b>	Mayuresh Gadre

### Telecon Body:

**From:** Baldwin, Brenda  
**Sent:** Thursday, October 29, 2015 7:52 PM  
**To:** GADRE, MAYURESH (mayuresh.gadre@novartis.com)  
**Cc:** Garnett, Theodore  
**Subject:** BLA 125510 Fluad PMRs

Hi Mayuresh,

Attached is our identification of postmarketing requirements for Fluad.  
Reference is made to the protocol for the Fluad confirmatory efficacy trial in

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adults 65 years of age and older submitted to IND (b) (4). Reference is also made to the agreed Pediatric Study Plans (PSPs) and to the protocols for the two Fluad trials in children 6 to < 72 months of age submitted to IND 14368 and/or (b) (4). Please note that the trials in children 0 to < 9 years of age have been changed to a deferral as we have determined that the planned trials with Fluad (quadrivalent) will satisfy the requirement for an assessment of safety and effectiveness of Fluad in this pediatric sub-population.

Your commitment to these PMRs will need to be provided officially as an amendment to the BLA by no later than November 6, 2015.

Regards,  
Brenda

Dr. Brenda R. Baldwin  
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