

# 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>	14-AUG-2015 01:42 PM
<b>Author</b>	BALDWIN, BRENDA
<b>EDR</b>	No
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	
<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 to submit repro developmental tox study
<b>FDA Participants</b>	Brenda Baldwin, Theodore Garnett
<b>Applicant Participants</b>	Mayuresh Gadre

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

**Sent:** Friday, August 14, 2015 10:09 AM

**To:** GADRE, MAYURESH

**Cc:** Garnett, Theodore

**Subject:** BLA 125510

## **RECORD OF TELEPHONE CONVERSATION**

Hi Mayuresh,

As discussed yesterday:

- We have determined that Section 8.1 (Pregnancy) needs to be part of the label. Because the BLA was submitted prior to the PLLR final rule (79 FR 72064, published December 4, 2014) we will either give Section 8.1, a pregnancy category B or C. We are aware that you have performed a Reproductive and Developmental Toxicity Study with FLUAD (AB09779) and a report has been prepared. You can submit this final report to the BLA for us to consider a pregnancy category B, or alternatively if you choose to not provide the report, we will use the pregnancy category C. If you will be providing the report to the BLA, we will need to receive it in the next couple of weeks. Please respond.
- The Late Cycle Meeting between CBER and Novartis has been scheduled for September 3, 2015 from 2:30 to 4 pm. If you would like to include any items in the agenda for this meeting, please inform us by September 1, 2015.

Regards,

Brenda