

RECORD OF TELEPHONE CONVERSATION

Submission Information

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

Telecon Details

Telecon Date/Time	21-OCT-2015 12:29 PM
Author	BALDWIN, BRENDA
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	OT -
Related STNs	None
Related PMCs	None
Telecon Summary	Disallow egg (b) (4)
FDA Participants	Brenda Baldwin
Applicant Participants	Mayuresh Gadre

This call was placed to discuss the recent submission to the BLA (Amend 24) in which Novartis indicated that the Fluad lots received by CBER on September 3, 2015 for in-support testing were manufactured with the changes listed in the table.” The last change listed in the table is (b) (4) in number of eggs inoculated and incubated in upstream manufacturing from approximately (b) (4) to approximately (b) (4) I noted that (b) (4)

As such the current Fluad BLA approval could not include this change. Mayuresh stated that the change in the number of eggs was not meant to be incorporated

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in the manufacturing section of the BLA, but was only meant to inform CBER that the lots submitted for testing included the 3 approved changes and (b) (4). He agreed that Novartis would submit this change as a supplement to the BLA following approval.