

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	15-OCT-2015 02:00 PM
Author	BALDWIN, BRENDA
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	OT -
Related STNs	None
Related PMCs	None
Telecon Summary	Request for soft launch denied.
FDA Participants	Brenda Baldwin, Theodore Garnett
Applicant Participants	Mayuresh Gadre

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

Sent: Thursday, October 15, 2015 2:47 PM

To: Baldwin, Brenda

Cc: Garnett, Theodore

Subject: FLUAD STN 125510 - Proposal for soft launch in 2016 following approval

Dear Brenda,

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The Company is proposing a soft launch of up to two lots of Fluad in 2016 provided approval of the Fluad BLA is received in 2015. The vaccine composition will include the following WHO 2015/2016 NH recommended strains:

- H1N1: A/California/7/2009 NYMC X-181 (an A/California/7/2009 pdm09-like virus).
- H3N2: A/Switzerland/9715293/2013 NIB-88 (an A/Switzerland/9715293/2013-like virus).
- B strain: B/Brisbane/9/2014 wild type (a B/Phuket/3073/2013-like virus).

In preparation for the proposed launch, The company would like to request the following support from CBER:

- SRID Testing of 3 monovalent lots (1 per strain) by mid November 2015.
- Lot release of up to (b) (4) lots of Fluad by end of January 2016.

The Company will provide the seed derivation and passage history and CBER confirmation of identity for the three strains to support the soft launch. Does CBER agree?

Please let me know if you have any questions or concerns.

Best Regards,
Mayuresh

From: Baldwin, Brenda
Sent: Wednesday, October 21, 2015 4:03 PM
To: 'GADRE, MAYURESH'
Cc: Garnett, Theodore
Subject: RE: FLUAD STN 125510 - Proposal for soft launch in 2016 following approval

Hi Mayuresh,

We do not agree with your proposal. As you recall, during the mid-cycle communication you indicated that you were not planning to manufacture any lots for the upcoming season, and as such you would have no launch lots for CBER to analyze. Because of this unique situation, we agreed to analyze small scale formulations with the understanding that we would be testing 3-5 monovalent lots at the time of the 2016-2017 season strain change, as well as multiple launch lots (made from multiple monovalent bulk lots) representing the licensed manufacturing process.

If you desire to have a soft launch of Fluad, you will need to submit a strain change supplement (PAS) to STN 125510 post-approval. This supplement (with accompanying samples) will need to undergo the usual rigorous review and testing.

Regards,
Brenda