

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	13-AUG-2015 02:20 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	Agree with submission of facility change info.
FDA Participants	Brenda Baldwin, Theodore Garnett
Applicant Participants	Mayuresh Gadre

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

Sent: Thursday, July 30, 2015 2:29 PM

To: Baldwin, Brenda

Cc: Garnett, Theodore

Subject: FLUAD BLA 125510 CMC question

Hi Brenda,

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Following up on our phone conversation earlier in the week, Novartis proposes to make a CMC change; to change the final vaccine release site from (b) (4) [REDACTED]. Please note there are no changes proposed to the release testing assays but only a transfer of release activity (for e.g. review of batch production records etc.). All the tests and the manufacturing activities remain the same. The nature of this change warrants a change in the eCTD section 3.2.P.3.1 (Manufacturers for Drug Product) to update the responsibilities of the (b) (4) site (Novartis Vaccines and Diagnostics (b) (4)) and (b) (4) site (Novartis Vaccines and Diagnostics Ltd.).

Can Novartis update this information as an amendment to the BLA?

Best Regards,
Mayuresh

From: Baldwin, Brenda [<mailto:Brenda.Baldwin@fda.hhs.gov>]
Sent: Monday, August 03, 2015 2:22 PM
To: GADRE, MAYURESH
Cc: Garnett, Theodore
Subject: RE: FLUAD BLA 125510 CMC question

Hi Mayuresh,

Before we will consider any changes to the CMC section of the BLA, please provide the following:

1. What is the primary purpose for wanting to implement this change now?
2. Have you established adequate quality unit and related procedures to conduct the extra Fluad product release functions at the proposed (b) (4) site.
3. Explicitly specify all of the changes that are involved with regards to the change of the final vaccine release site from (b) (4) [REDACTED].

Please provide your response via e-mail to me for our consideration by no later than COB August 6, 2015.

Regards,
Brenda

From: GADRE, MAYURESH [<mailto:mayuresh.gadre@novartis.com>]
Sent: Thursday, August 06, 2015 10:26 AM
To: Baldwin, Brenda
Cc: Garnett, Theodore
Subject: RE: FLUAD BLA 125510 CMC question

Hi Brenda,

Here are the company responses to your questions regarding the proposed CMC change:

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Question # 1:

What is the primary purpose for wanting to implement this change now?

Response to Question 1:

The Company wishes to implement this change for business purposes as a result of the recent business transaction between GSK and Novartis, which included the transfer of (b) (4) manufacturing and quality operations from Novartis to GSK in March 2015.

Question # 2:

Have you established adequate quality unit and related procedures to conduct the extra Flud product release functions at the proposed (b) (4) site?

Response to Question 2:

This change has been managed through change control management in order to evaluate all Quality and Regulatory aspects. An adequate quality unit and related procedures are in place at the (b) (4) site in order to conduct product release activities.

Question # 3:

Explicitly specify all of the changes that are involved with regards to the change of the final vaccine release site from (b) (4)

Response to Question 3:

(b) (4) will be added to Flud license as the batch releasing site (replacing (b) (4)) and as part of this, the following responsibilities will move to (b) (4) site:

- submission of Lot Release Protocols
- release of bulk, fill and finished products to market
- management and investigation of PTCs and adverse events

The m3 dossier sections "3.2.P.3.1 Manufacturer(s)" and new Lot Release Protocol from (b) (4) will be amended accordingly. Please note that an updated lot release protocol will be provided within the response to the Flud BLA information request received on 29th July 2015.

As part of this change there are no modifications to any manufacturing process, equipment, facilities or utilities.

Please let me know if you have any additional questions.

Best Regards,
Mayuresh

From: Baldwin, Brenda [<mailto:Brenda.Baldwin@fda.hhs.gov>]
Sent: Thursday, August 13, 2015 12:11 PM
To: GADRE, MAYURESH
Cc: Garnett, Theodore
Subject: RE: FLUAD BLA 125510 CMC question

Hi Gadre,

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We agree that you may amend the CMC section of the BLA with this change.

Regards,
Brenda