

RECORD OF TELEPHONE CONVERSATION

Submission Information

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| 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

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|---------------------------------|---|
| Telecon Date/Time | 21-OCT-2015 05:01 PM |
| Author | BALDWIN, BRENDA |
| EDR | No |
| Post to Web | No |
| Outside Phone Number | |
| FDA Originated? | No |
| Communication Categories | IR - Information Request |
| Related STNs | None |
| Related PMCs | None |
| Telecon Summary | Questions on filters used for MF59 (b) (4) and sterilization. |
| FDA Participants | Brenda Baldwin |
| Applicant Participants | Mayuresh Gadre |

From: Baldwin, Brenda

Sent: Wednesday, October 21, 2015 1:23 PM

To: GADRE, MAYURESH (mayuresh.gadre@novartis.com)

Subject: BLA 125510

In our review of your BLA for Fluad, we have noticed an issue with the results obtained in the (b) (4) performed on (b) (4) of the (b) (4)

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(b) (4) used in the MF59C.1 adjuvant process validation, specifically:

(b) (4)

You state that the initial (b) (4) showed removal of the (b) (4) in (b) (4) of the (b) (4) (b) (4) (page 12/section 3.2.S.2.5), while the (b) (4) showed no reduction at all. An investigation concluded that improper installation of the filter in the disc holder was the root cause of failure. After a new disc holder was designed and qualified, the (b) (4) was repeated, and (b) (4) test filters failed the test. You concluded that the filter was suitable for (b) (4) and stated that an alternate sealing assembly should be qualified for use and the test should be performed in its entirety one more time.

Because you have failed the (b) (4), we request that you perform the additional test as mentioned above (an alternate sealing assembly should be qualified for use and test should be performed in its entirety one more time) before using the (b) (4) for routine production. You may file the additional test results as a post-marketing commitment after the approval of this vaccine.

(b) (4) :

On page 11, section 3.2.S.2.5, you state that none of the (b) (4) tested completely retained the (b) (4), therefore the filter was deemed unsuitable for sterilization; however, you note that sufficient retention was shown to support its use for (b) (4) (see data below from attachment 16). The acceptance criteria of (b) (4) was not met (see data below from attachment 16). You note that (b) (4) elements in series might theoretically retain the required challenge level of (b) (4) effective filtration area.

Because you have failed the (b) (4) (failed to retain (b) (4)), we recommend that you prepare a test protocol and demonstrate the actual (b) (4) based on established acceptance criteria. You may file additional (b) (4) results (to demonstrate predetermined (b) (4) as a post-marketing commitment after the approval of this vaccine. In addition, please provide your data to support your conclusion that the (b) (4) elements in series might theoretically retain the required challenge level of (b) (4) effective filtration area. You may file this data as a post-marketing commitment after the approval of this vaccine.

(b) (4)

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(b) (4)

Please confirm receipt of this e-mail and indicate your commitment to performing these tests on the (b) (4). Please note that the (b) (4) cannot be used until additional (b) (4) tests are completed and found acceptable. The (b) (4) can be used for the stated dual purpose of (b) (4) in the (b) (4) of the MF59C.1 (b) (4).

Please additionally provide clarification on the filter currently used in the sterile filtration of the MF59C.1 adjuvant (b) (4) prior to formulation with the antigens.

If you would like to discuss further, we can make ourselves available for a teleconference in the next few days.

Dr. Brenda R. Baldwin