

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125510/0 Office: OVRR

Product:
Influenza Vaccine, Adjuvanted

Applicant:
Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 20-April-2015 3:33 PM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):
1. Other

Author: Theodore Garnett

Telecon Summary:
Response to question regarding Fluad samples for CBER testing

FDA Participants: Theodore Garnett

Non-FDA Participants: Mayuresh Gadre

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Garnett, Theodore
Sent: Monday, April 20, 2015 3:33 PM
To: 'GADRE, MAYURESH'
Subject: Response to question regarding Fluad samples for CBER testing

Dear Mayuresh,

The following is CBER's response to Dr. Johnson's proposal in his e-mail to Dr. Manju dated 16 April 2015 (included below):

Novartis Proposal:

Following discussion with our Quality team they have requested (following agreement with yourselves) that testing is performed on a (b) (4) sample made up from the lots sent to CBER. The proposal is that the (b) (4) lots are made by (b) (4)

(b) (4) to give the (b) (4) lots generated in both laboratories and then perform the SRID analysis. Can I therefore ask if this approach is acceptable to CBER.

CBER Response:

As we had indicated earlier, our purpose of getting these lots was for establishing the assay for adjuvanted product in our laboratory. We agree to your proposal of making (b) (4) lots by (b) (4) a (b) (4) of the lots that were supplied (b) (4) to give the (b) (4) lots generated in both laboratories and then perform the SRID analysis. We look forward to getting your SRID results for (b) (4) lots.

Regards,
Ted

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Admin/Finance Section, Home Support Branch Director

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From: Johnson, Neil-1 [<mailto:neil-1.johnson@novartis.com>]
Sent: Thursday, April 16, 2015 4:00 PM
To: Joshi, Manju
Cc: King, Jane; GADRE, MAYURESH
Subject: Fluad samples for CBER testing

Dear Dr. Joshi

Firstly, I am Dr Neil Johnson, and am the Head of Regulatory CMC and Compliance at Novartis Influenza Vaccines. I understand that my colleague Jane King has been in contact with you previously regarding the supply of Flud samples.

I apologise for the delay in sending across the potency values for the Flud samples you have been supplied with. The delay in obtaining results is due to discussions within our Quality group as the lots supplied were commercial lots from the EU 2014/15 NH campaign and are still within expiry. The concern is that within Novartis we have an internal Quality policy on generating additional data on lots post marketing. Following discussion with our Quality team they have requested (following agreement with yourselves) that testing is performed on a (b) (4) sample made up from the lots sent to CBER. The proposal is that the (b) (4) lots are made by (b) (4) of the lots supplied (b) (4) to give the (b) (4) lots generated in both laboratories and then perform the SRID analysis. Can I therefore ask if this approach is acceptable to CBER. If it is our QA department will approve the analysis required here in (b) (4) and we will be able to provide results within 7 days.

Again I apologise for the delay and for the additional request to your laboratory.

I look forward to receiving your response.

Kinds regards

Neil I. Johnson, PhD
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