

(System Info - 211157 BALDWIN BRENDA 08/27/2012 13:19:33 BALDWIN)

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125408/0 Office: OVR

Product:
Influenza Vaccine (MDCK Cells)

Applicant:
Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 19-Jun-2012 01:56 AM Initiated by FDA? No

Telephone Number:

Communication Category(ies):
1. Other - release tests - NVD questions regarding incorporation

Author: BRENDA BALDWIN

Telecon Summary:
QC testing procedures

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

E-mail Body:

From: Gollwitzer, Matthew [<mailto:matthew.gollwitzer@novartis.com>]

Sent: Tuesday, June 19, 2012 1:56 PM

To: Baldwin, Brenda

Cc: Fritz, Timothy

Subject: Manufacture of Optaflu Commercial Batches

Sensitivity: Confidential

Dear Brenda and Tim,

Novartis would like to communicate to CBER its intent to manufacture while the BLA review is ongoing. Since it is our intent to supply cell based vaccine for 2012-2013 season we need to start manufacture campaigns shortly in June. Novartis also wishes to communicate most of the additional acceptance criteria, as requested by CBER, will be included as communicated by Novartis via BLA amendments for the release of monovalent as well as trivalent formulated

bulk. However, there are certain specifications communicated by CBER that NVD will not be able to incorporate into this year's commercial campaign due to the time restrictions. Novartis wishes to discuss these pending specifications and receive FDA feedback on the commercial material intended for manufacture this month.

Kind Regards,

Matt

From: Baldwin, Brenda [mailto:Brenda.Baldwin@fda.hhs.gov]
Sent: Friday, June 29, 2012 4:53 PM
To: Gollwitzer, Matthew
Subject: RE: Manufacture of Optaflu Commercial Batches
Sensitivity: Confidential

Hi Matt,

Please submit the specific questions you may have regarding the specifications you intend to use with this year's commercial material to Dr. Timothy Fritz and me via e-mail. We will respond as soon as possible to your stated questions. If a teleconference is still needed, we will set one up at a convenient time for both Novartis and CBER. Have a good weekend.

Regards,
Brenda

From: Gollwitzer, Matthew [mailto:matthew.gollwitzer@novartis.com]
Sent: Monday, July 09, 2012 11:13 AM
To: Baldwin, Brenda
Cc: Fritz, Timothy
Subject: RE: Manufacture of Optaflu Commercial Batches
Sensitivity: Confidential

Dear Brenda,

I have provided an attachment in response to your email below. Although NVD does not have any specific questions at this time regarding the proposed testing/specifications, we just wanted to highlight that not all the additional testing that CBER has requested can be incorporated into this year's commercial campaign.

The attachment I have provided is color coded as follows:

- All testing in green are included as part of this year's commercial campaign.
- All testing in blue are additional tests that CBER has requested to be incorporated as part of release:
 - The tests highlighted in blue with black text can and will be incorporated into this year's campaign

o The tests highlighted in blue with red text either cannot be incorporated into this year's campaign or NVD is waiting for CBER feedback. We have provided our responses officially as part of sequence 0010 and 0012 so I assume the CBER review team is still discussing.

Kind Regards,

Matt

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|-----------------------|----------------------------------|---------|
| Level | Method | Remarks |
| (b) (4) (b)(4) | | |
| FCC filling lot | sterility | None |
| | endotoxin | None |
| | General Safety | None |
| | appearance | None |
| | Extractable volume | None |
| packaged material | Hemagglutinin antigen (identity) | None |