

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: 30-January-2015 11:09 AM Initiated by FDA? Yes

Telephone Number: N/A – E-mail communication

Communication Category(ies):
1. Information Request

Author: Pankaj (Pete) Gollwitzer

Telecon Summary:
Request to determine the need for facilities inspection

FDA Participants: Pete Amin, Marion Michaelis, Brenda Baldwin, Kirk Prutzman

Non-FDA Participants: Matthew Gollwitzer

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Amin, Pankaj (Pete)
Sent: Friday, January 30, 2015 11:09 AM
To: Gollwitzer, Matthew (matthew.gollwitzer@novartis.com)
Cc: Michaelis, Marion; Baldwin, Brenda; Prutzman, Kirk C
Subject: Novartis 125510 BLA - Information Request

Good Morning,

We have Information request for the following production facilities involve in this BLA. Purpose for this request to determine the need for facilities inspection, Please provides response by 02/09/2015.:

Novartis Vaccines and Diagnostics (b) (4)

[REDACTED]

(b) (4)

Novartis Vaccines and Diagnostics Ltd

(b) (4)

Novartis Vaccines and Diagnostics (b) (4)

Novartis Vaccines and Diagnostics (b) (4)

For each of four facilities, please provide following information:

1. Inspection history (last two years). Please provide inspection dates, investigators name, and inspection outcome.
2. The establishment is performing any significant manufacturing step(s) in new (unlicensed) areas?
3. The establishment is performing any significant manufacturing step(s) using different equipment?
4. The establishment is performing any significant manufacturing step(s) that are currently dedicated areas that have not been approved as multi-product facilities /buildings/areas?
5. The manufacturing process is sufficiently different (new production methods, specialized equipment or facilities) from that of other approved products produced in the facility?

Please let me know if you need any clarification.

Pete

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