

Information Request Email, Drug Product Testing, September 12, 2014 - BEXSERO

- RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125546/0 Office: OVRR

Product:

Meningococcal Group B Vaccine

Applicant:

Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 12-Sep-2014 04:50 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary:

IR regarding drug product testing

FDA Participants: KIRK PRUTZMAN, ED WOLFGANG, RAMACHANDRA NAIK

Non-FDA Participants: PATRICIA STOEHR

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Prutzman, Kirk C

Sent: Friday, September 12, 2014 4:50 PM

To: Stoehr, Patricia (patricia.stoehr@novartis.com)

Cc: Wolfgang, Edward; Naik, Ramachandra

Subject: STN 125546 - Information Request

Dr. Stoehr,

Please find attached a request for additional information regarding STN 125546 (Meningococcal Group B Vaccine). Please provide your responses to this information request in an Amendment to STN 125546 by September 26, 2014. If you have any questions about this communication, please contact Kirk Prutzman, Ramachandra Naik, or Ed Wolfgang at (301) 796-2640.

Regards,

Kirk Prutzman, PhD

Primary Reviewer/Regulatory Project Manager

CBER/OVRR/DVRPA/CMC3

Food and Drug Administration

10903 New Hampshire Avenue

Building 71 and Room 3041

Silver Spring, MD 20993-0002

Phone: (301) 796-2640
Fax: (301) 595-1244

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF VACCINES RESEARCH AND REVIEW
DIVISION OF VACCINES AND RELATED PRODUCTS APPLICATIONS

DATE: SEPTEMBER 12, 2014 PAGES: 3

TO: NOVARTIS VACCINES AND DIAGNOSTICS, INC

ATTENTION: PATRICIA STOEHR, PH.D.

Senior Group Manager Regulatory Affairs

Novartis Vaccines & Diagnostics

350 Massachusetts Avenue

Cambridge, MA 02139

USA

FAX: (617) 871-8060 TEL: (617) 871-4711

FROM: KIRK PRUTZMAN, PH.D.

Regulatory Project Manager

FAX: (301) 595-1244 TEL: (301) 796-2640

SUBJECT: STN: BL 125546/0 – Request For Information

MESSAGE:

Dear Dr. Stoehr:

MESSAGE:

Dear Dr. Stoehr:

We have the following request for additional information regarding STN 125546 (Meningococcal Group B Vaccine):

1. -----(b)(4)----- assay for drug product

This method is validated as a quantitative assay for drug product release. However, linearity and range were not evaluated. Please provide data to establish linearity and range of the assay using the product.

2. -----(b)(4)-----

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3. -----(b)(4)-----

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a. -----(b)(4)-----
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b. -----(b)(4)-----
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c. -----
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d. -----
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4. -----(b)(4)-----

------(b)(4)-----,

a. -----

(b)(4)-----

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b. -----
------(b)(4)-----

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Please provide your responses to this information request in an Amendment to STN 125546 by September 26, 2014. We recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions about this communication, please contact Kirk Prutzman, Ramachandra Naik, or Ed Wolfgang at (301) 796-2640.