

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

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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.