

Information Request Email, November 6, 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: 06-Nov-2014 04:06 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary:

IR regarding -----(b)(4)----- and Rosia Facilities

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: Thursday, November 06, 2014 4:06 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 November 17, 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: NOVEMBER 6, 2014 PAGES: 4

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

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:

We have the following request for additional information regarding your submission of
Biologics License Application STN 125546 (Meningococcal Group B Vaccine):

Regarding Your ----(b)(4)---- Facility:

Reference your -----(b)(4)-----:

1. Please confirm that -----(b)(4)----- are dedicated to the 4CMenB Recombinant proteins only. Please provide a summary of the sanitization procedures and storage conditions of the resins and the qualification of those procedures and conditions.

Reference Processing filters:

2. Please confirm that processing filters are dedicated to the 4CMenB Recombinant proteins only. Please provide a summary of the sanitization procedures, storage conditions, reuse of processing filters and the qualification of those procedures and conditions.

Reference Processing Equipment:

3. Please provide a list, in table format, of the product contact equipment or containers (including Glass) used in 4CMenB Recombinant Proteins manufacturing and specify any other products that are manufactured in that same equipment /container. (Note: you have not distinctly identified what other products are shared on specific product contact equipment /containers in the submission or any other previous communication)

Reference Cleaning Validation:

4. Please provide justification for your acceptance criteria for Purification Equipment as follows:

Visual Inspection (b)(4) ---(b)(4)--- (b)(4) ---(b)(4)---

Clean (b)(4) ---(b)(4)--- (b)(4) -----(b)(4)-----
----- (b)(4)-----

Reference Process Intermediate ---(b)(4)--- based on Microbial Test Data:

5. Refer to 3.2.S.2.5 Process Validation & Evaluation [rp961 – -(b)(4)-]; Page 58 of 66: You performed a microbiological --(b)(4)-- study (rp961c intermediates --(b)(4)-- with (b)(4) scale batches) to confirm the ability to -----(b)(4)----- ----- hours within their respective process containers with no significant increase in ----(b)(4)----. Were similar studies performed for rp287-953 and rp936-741?

Regarding Your Novartis Rosia Facility:

Reference Final Drug Product Container Closure:

6. Please provide a summary of the Incoming Testing / Release Requirements for the Syringe and Stoppers

Reference Processing Equipment:

7. Please provide a list, in table format, of the product contact equipment or containers (including Glass) used in OMV manufacture and 4CMenB Formulation /Fill and specify any other products that are manufactured in that same equipment or container. (Note: you have not distinctly identified what other products are shared on specific product contact equipment /containers in the submission or any other previous communication)

Reference Cleaning Validation:

8. Reference Table 3.2.A.1.4.2.6.1.9.2-4 Cleaning Validation Results for ----- (b)(4)----- After the Restart of the Area: Please explain why (b)(4) was not tested and /or reported.
9. You state that “Cleaning Revalidation activity, demonstrating the cleaning procedure efficacy to remove residual product processing OMV-NZ from the ----- -(b)(4)-----, is still on-going due to DR 203052.” Please provide a summary of Deviation, and when cleaning validation activities are expected to be completed.
10. Please provide your justification for not analyzing (b)(4) on rinse water in Cleaning Validation for -----(b)(4)-----, as applicable)

Reference CCIT for Prefilled Syringe:

11. Reference your new -----(b)(4)----- method (SOP 295059 / report 296376). You implemented a positive control to increase assay sensitivity to detect minute leaks in the closure system using a -----(b)(4)----- . How did you determine that a (b)(4) leak defect size is your critical (worst case) leak? To support test sensitivity, we recommend -----(b)(4)----- of your positive control; have you considered this range of leak diameter for your positive control?
12. Please provide a complete description of your CCIT ---(b)(4)--- Method outlining all steps and parameters (including Equipment and materials used, vacuum/ pressure stresses, exposure times, (b)(4) detection method, Limit of Detection, etc.).

Please provide your responses to this information request in an Amendment to STN 125546 by November 17, 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, Ed Wolfgang, or Ramachandra Naik at (301) 796-2640.