

Information Request Email, November 7, 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: 07-Nov-2014 01:21 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary:

IR regarding LRP

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, November 07, 2014 1:21 PM

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

Cc: Wolfgang, Edward; Naik, Ramachandra

Subject: STN 125546 - LRP Information Request / Comments

Dr. Stoehr,

CBER has reviewed the templates for the Final Container and all four bulks and has the following comments:

1. On the first page of each bulk template (MEN B RECOMBINANT PROTEIN 961c CONCENTRATED BULK LOT, MEN B RECOMBINANT PROTEIN 287 – 953 CONCENTRATED BULK LOT, MEN B RECOMBINANT PROTEIN 936 - 741 CONCENTRATED BULK LOT and MEN B OMV NZ C CONCENTRATED BULK LOT) please add the **Reason for submission** check boxes at the top (the same as for the final container lot release protocol template) and the signature of the Authorized Official (Qualified Person), and the date for the bulks at the bottom of the page.
2. Also on the first page of each bulk template we will need a small table with all of the bulks identified and the one being submitted checked off. This allows the person entering the data to know that this needs to be added to the system. This name will

appear on the release letter for each bulk so please let us know if you would like something different than what is being suggested below.

- RP 961c
- RP 287-953
- RP 936-741
- OMV NZ

3. For the templates for concentrated bulks (MEN B RECOMBINANT PROTEIN 961c CONCENTRATED BULK LOT, MEN B RECOMBINANT PROTEIN 287 – 953 CONCENTRATED BULK LOT, MEN B RECOMBINANT PROTEIN 936 - 741 CONCENTRATED BULK LOT) the --(b)(4)-- test is missing the result for --(b)(4)--- type. Please include the test result for --(b)(4)-- type based on your--(b)(4)-- test qualification according to SOP 202289.
4. We currently have no comments on the lot release protocol for the final container.
5. The review of this submission is on-going and more changes may be requested as the review progresses.

When submitting lot release protocols for samples submitted during the BLA review process please use the check box **For licensing action** and not For release. The STN: should be 125546/0 and if samples are sent with a subsequent supplement the STN would look like this example 125546/5001. If the lots submitted during the review are found to be acceptable they will be released at the time of the BLA approval.

Please also note in correspondence or labels sent to the sample custodian the product name used should always be the proper licensed name and not the trade name.

Please provide your responses to this information request in an Amendment to STN 125546 by November 21, 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

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