

Teleconference Summary, December 16, 2014 - BEXSERO

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

Date: January 5, 2015

Subject: BLA 125546/0 summary of the December 16, 2014, teleconference

FDA Participants:

Ramachandra S. Naik
Kirk C. Prutzman
Edward Wolfgang
William McCormick
Muhammad Shahabuddin
Anil Choudhary

Novartis Participants:

Leonardo Gherardini (Quality)
Cristina Mariotti (Quality Control)
Chiara Villani (Technical Operations)
Joe Crowell (Program Management)
Sue Fekete (Regulatory)
Janne Uldal (Regulatory CMC)
Mary McGovern (Regulatory)

Background and Objectives:

On December 15, 2014, Ms. Susan Fekete with Novartis Vaccines and Diagnostics, Inc. was contacted by CDR Wolfgang concerning CBER's comments listed below and to arrange a teleconference. A teleconference was held on December 16, 2014, at 0900. CBER's questions are listed below in plain text and discussions that occurred during the meeting are listed below in **bold**.

Regarding SOP 228563 (Identity of Tetravalent vaccine- 287-953, 936-741, 961c, NZ-OMV- against meningococcus serogroup B ---(b)(4)-- , product in vial and packaged product) by ---(b)(4)---:

1. Under section 4.1 (Preparation of Reagents and Solutions) - We are unable to replicate the use of -----(b)(4)----- for dissociation of the recombinant proteins from the (b)(4)----- in final product, prior to -----(b)(4)-----, for Identity testing by ---(b)(4)---. Please clarify if we are missing any information in the protocol submitted in the BLA.
2. Under section 4.1 (Preparation of Reagents and Solutions)- the composition of - (b)(4)- (b)(4) is missing. This (b)(4) is used for anti-OMVZ primary antibody -(b)(4)- (pg.14 of SOP).

Meeting Discussion: CBER summarized comment #1 and asked Novartis if they have any explanation why CBER could not reproduce the use of -----(b)(4)-----, and that the composition of --(b)(4)-- is missing in the BLA submission. Novartis replied the SOP contains typographic errors and that the (b)(4) listed under

section 4.1 should be (b)(4) and not (b)(4), as indicated. Also, in section 4.3 of the SOP the -----(b)(4)----- should be -----(b)(4)----- as it is currently written.

CBER expressed concern about the (b)(4) used to dissociate/extract recombinant proteins from the ---(b)(4)-- and validity of using -----(b)(4)----- . Novartis said they need to further research this question and discuss it internally before responding.

Novartis agreed to submit a response to CBER's comments later today or tomorrow via email and as an official amendment to the BLA. A clean version and a tracked changes version of SOP 228563 will be provided.