

# 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.