

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125363/0 Office: OVRR

Product:

Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine

Applicant:

GlaxoSmithKline Biologicals

Telecon Date/Time: 26-May-2011 01:00 PM Initiated by FDA? Yes

Telephone Number: -----b(4)-----

Communication Category(ies):

1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary:

CBER request for updated product manufacturing status

FDA Participants: KIRK PRUTZMAN, JOSEPH TEMENAK, WILLIE VANN, JENNIFER BRIDGEWATER, RAJESH GUPTA, KAREN CAMPBELL, WILLIAM MCCORMICK

Non-FDA Participants: JODY ANN GOULD, NORRIS PYLE, XAVIER RAQUET, KALLIOPI GRIGORIADOU

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

CBER requested a tcon with GSK to discuss manufacturing issues with the Menhibrix vaccine product.

*Question 1 (CBER): Willie Vann asked GSK if there were any manufacturing changes to Menhibrix since the prior submission.*

GSK Response: GSK said there were **NO MANUFACTURING CHANGES** to Menhibrix and that the manufacturing process was exactly the same as it has been in the past.

*Question 2 (CBER): Rajesh Gupta asked if the samples of Menhibrix provided 2 year ago were still representative of current manufacturing process.*

GSK Response: They are still representative of current manufacturing process.

*Question 3 (CBER): Rajesh Gupta asked if GSK was planning on manufacturing new launch lots.*

GSK Response: GSK is planning on manufacturing new launch lots of Menhibrix and they said they would send samples to CBER at the appropriate time. CBER agreed.

*Question 4 (CBER): Rajesh Gupta asked how many lots per year of Menhibrix GSK was planning to manufacture upon approval.*

GSK Response: GSK was not sure but promised to provide this information at a later date

*Question 5 (GSK): GSK asked if CBER needs new samples of the bulk conjugate for testing.*

CBER Response: Yes. CBER also needs new test reagents.

Call Ended.