

Record of Telephone Conversation, March 11, 2011 - MenHibrix

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: 11-Mar-2011 04:15 PM Initiated by FDA? Yes

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

Communication Category(ies):

1. Advice

Author: KIRK PRUTZMAN

Telecon Summary:

Communication of CBER advice for CR letter responses

FDA Participants: KIRK PRUTZMAN, JOSEPH TEMENAK, WILLIE VANN, JENNIFER BRIDGEWATER

Non-FDA Participants: JODY ANN GOULD, NORRIS PYLE

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Background:

On June 11, 2010 CBER issued a complete response (CR) letter to GlaxoSmithKline (GSK) biological licensing application (BLA) STN 125363/0 for Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine (MenHibrix). In the CR letter, CBER identified 88 items that needed to be addressed before MenHibrix could be approved for licensure. Because the scope of the issues in the CR letter was so large, CBER and GSK agreed to try to resolve them by GSK submitting a preliminary response to the CR letter as an amendment to IND --b(4)---. Additionally, GSK submitted serology data for review on June 4, 2011 (1 week prior to CBER issuing a CR letter) that was not fully reviewed prior to issuing the CR letter. CBER agreed to attempt to review this serology data in addition to the responses to the CR letter. The primary issues identified by CBER were a lack of a satisfactory assay to identify --b(4)----- -- in the final product and a lack of serology data indicated that the vaccine was inducing protective immunity. CBER agreed to try to review GSK's responses to the CR letter under IND --b(4)- to the best of their ability within a 60 day window. On December 28, 2010, GSK submitted responses to the CR letter as an amendment to IND --b(4)-- (amendment 171).

Telecon Discussion:

On March 11, 2011 CBER (Kirk Prutzman, Joseph Temenak, Willie Vann, Jennifer Bridgewater) called GSK (Jody Ann Gould, Norris Pyle) to discuss CBER's review of IND --b(4)----- CBER made the following points:

1. Regarding the –b(4)----- assay, CBER indicated that GSK's responses were sufficient for GSK to proceed with a complete response to the CR letter. Joseph Temenak clearly stated that CBER's acknowledgment that it was sufficient for GSK to proceed with a complete response to the CR letter was not an indication that GSK's current responses were sufficient for licensure. Joseph Temenak further indicated that during the review period for GSK's CR response, additional concerns/issues with the –b(4)----- assay may arise. Willie Vann indicated that it may be possible to resolve –b(4)----- release test issues in the BLA review process.
2. CBER indicated that they did not have any information to relay regarding the serology data.

GSK indicated that they understood CBER's points. CBER asked GSK when they planned to submit their response to the CR letter. GSK indicated that they were planning to submit a complete response around mid-April, 2011. GSK also requested that CBER communicate review questions as soon as they arise during the review period rather than near the end of the review period. CBER acknowledged the request. On March 14, 2011 GSK emailed their version of this phone call. It is copied below:

RECORD OF FDA TELECONFERENCE

Date: March 11, 2011

Subject: Teleconference to discuss MenHibrix Complete Response

Participants:

CBER:

Jennifer Bridgewater (Consumer Safety Officer)

Kirk Prutzman (Project Manager)

Joseph Temenak (Project Manager)

Willie Vann (Supervisory Chemist, DBPAP/LBP)

GSK:

Jody Gould, Director, Vaccines, US Regulatory Affairs

Norris Pyle, Associate Director, Vaccines, US Regulatory Affairs

Product:

MenHibrix STN 125363, submitted August 12, 2009

Purpose of Meeting:

The purpose of the meeting was to discuss the following:

1. CBER's response to the December 28, 2010 IND amendment containing information regarding failed attempts to qualify a QC release test for free PS content on the final container vaccine, as well as information supporting –b(4)----- as a suitable alternative method for detecting degraded conjugate
2. Update on CBER's review of serology information submitted June 2010.

Discussion:

- CBER has reviewed the information submitted in the IND amendment and considers the data sufficient to allow GSK to move forward with submitting the complete response to the June 11, 2010 CR letter.
- CBER stressed that although CBER is allowing GSK to move forward with the complete response, this does not guarantee that there will be no issues or questions as they perform their review.
- Dr. Vann stated that there would be issues to resolve during the review period.

- GSK asked if CBER had any specific questions at this time that GSK could address while submitting the complete response – CBER does not.
- CBER has not reviewed the serology data submitted June 4, 2010 as they have given priority to reviewing the information in the December IND amendment. CBER again indicated this information would be reviewed with the CR letter response.
- CBER asked when GSK planned to submit the complete response. GSK stated mid-April.
- GSK stated that it would be helpful if CBER communicated any review questions throughout the review period as opposed to waiting until the end. CBER will take this under consideration.
Willie Vann issued some changes to the GSK telecon record (in bold/underlined/blue font). They are emailed to GSK.
- CBER stressed that although CBER is allowing GSK to move forward with the complete response, this does not guarantee that there will be no issues or questions **relating to free PS content** as they perform their review.
- Dr. Vann stated that there would be issues **relating to free PS content** to resolve during the review period.
- GSK asked if CBER had any specific questions at this time that GSK could address while submitting the complete response – CBER does not.