

Record of Telephone Conversation, August 16, 2011 - MenHibrix

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

Product:

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

Applicant:

GlaxoSmithKline Biologicals

Telecon Date/Time: 16-Aug-2011 02:52 PM Initiated by FDA? Yes

Telephone Number: jody.a.gould@gsk.com

Communication Category(ies):

1. Advice

Author: KIRK PRUTZMAN

Telecon Summary:

Email/tcon referenced in Amendment 15

FDA Participants: KIRK PRUTZMAN, JOSEPH TEMENAK, DAVID STATEN

Non-FDA Participants: JODY GOULD

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Prutzman, Kirk C

Sent: Tuesday, August 16, 2011 2:52 PM

To: 'Jody Gould'

Cc: Temenak, Joseph; Staten, David

Subject: RE: MenHibrix STN/BL125363

Hi Jody,

Thank you for putting this information together. I spoke with my supervisor and have the following responses.

1. Regarding your plan for adding clarification of the product labeling to instruct practitioners on MenHibrix reconstitution and your submission of supporting data:

We recommend that you submit this information to the BLA as you proposed. Your plan seems reasonable but we will need to review the revised PI and the supporting data before we can approve the changes. We will contact you with any issues or questions when we have had a chance to look at your changes.

2. Regarding your questions about your CMC responses to the CR-Letter:

We have not received final reviews from the CMC reviewers. Currently, there is no information to communicate regarding Post Marketing Commitments. We will communicate information as the reviews are finalized.

Regards,

Kirk Prutzman, PhD

Food and Drug Administration

Primary Reviewer/Regulatory Project Manager

CBER/OVRR/DVRPA/CMC3

1451 Rockville Pike (WOC2)
Room 2241
HFM-481
Rockville, MD 20857
Phone: (301) 796-2640

From: Jody Gould [mailto:jody.a.gould@gsk.com]

Sent: Monday, August 15, 2011 1:52 PM

To: Prutzman, Kirk C

Cc: Temenak, Joseph

Subject: MenHibrix STN/BL125363

Importance: High

Dear Kirk,

I received your email on August 2. Thank you for getting back to me. I am summarizing the information related to the proposed label for MenHibrix in this email. In addition, there are a few general questions related to the CMC review; I would appreciate any feedback/information on these.

MenHibrix PI

Background

Currently, the proposed MenHibrix PI indicates that practitioners should withdrawal 0.5 mL for administration, but without the instruction to switch to a ---b(4)----- for this measurement (note that GSK's --b(4)----- do not have graduation marks on them). Please note, this topic was discussed previously via teleconference with CBER in the context of the product labeling for Hiberix (STN 125347). Based on the Hiberix discussions, the following are planned for MenHibrix:

- Clarification of the product labeling to instruct practitioners to reconstitute the vaccine using the --b(4)----- of diluent provided, then withdrawal a measured amount using a -----b(4)-----.
- Supporting data for the amount of reconstituted vaccine to withdraw to ensure delivery of the nominal dose of antigens.

GSK's Proposal

GSK proposes to amend the BLA with the following information:

- A summary of data that supports withdrawal of a specified amount of reconstituted vaccine – this will be a m1.11.1 document, less than 20 pages in length. This summary will include proposed wording for the PI, but we will wait to provide a revised annotated PI until we receive other comments from CBER's review of the proposed labeling.

GSK would be happy to discuss this proposal with CBER representatives by phone at your earliest convenience.

Also, for your information, GSK is currently pursuing a diluent presentation in vials for both MenHibrix and Hiberix as a long-term solution to address measured withdrawal requirements. Data supporting the vial presentation are anticipated to be available later this year and we are presently planning to submit these to both BLAs in 4Q 2011 (after approval of the MenHibrix BLA).

Other questions – MenHibrix BLA

- In several of the CMC responses to the June 11, 2010 CR Letter, GSK proposed to submit CMC information as post-approval commitments. To facilitate internal planning, any current feedback regarding the acceptability of these proposed PMCs would be helpful.
- At the request of Dr. Gupta, GSK sent new reagents to CBER. We agreed to submit qualification reports associated with these reagents to CBER. These reports are currently being translated and will be submitted as an amendment to the BLA shortly. Please feel free to contact me with any questions.

Thanks again and kind regards,

Jody

Jody Ann Gould, PhD

Senior Director

US Regulatory Affairs

jody.a.gould@gsk.com

610-787-3765 (phone)

610-787-7063 (fax)

Trade secret and/or confidential commercial information contained in this message (including any attachments) is exempt from public disclosure to the full extent provided under law. If you are not the intended recipient of this message, or if you are not responsible for delivering it to the intended recipient(s), do not use, disclose, reproduce, or distribute this message (including any attachments). If you have received this message in error, please erase all copies (including any attachments) and notify me immediately. Thank you.