

Record of Email Communication, June 21, 2010 - MenHibrix

Date: June 21, 2010
From: David Staten, RPM
Category: Clarification request and FDA response
Summary:

On June 21, 2010, FDA received the following email from the sponsor requesting clarification on comments that were in our CR letter dated June 11, 2010. FDA responses are included in the body of the text.

From: Jody Gould [mailto:jody.a.gould@gsk.com] **Sent:** Monday, June 21, 2010 12:31 PM **To:** Staten, David **Cc:** Temenak, Joseph **Subject:** BLA STN 125363 - Request for Clarification **Importance:** High

Dear David,

As communicated in my voicemail this morning, GSK is respectfully requesting clarification of the following items from the June 11 CR letter.

Please contact me with any questions.

Thanks again for your help!

Jody

Jody Ann Gould, PhD Head, Neisseria Vaccines North American Regulatory Affairs
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Item 4

GSK uses the following parameters to define an individual 'assay run': -----(b)(4)-----
---. The variable -----(b)(4)-----
----- technician on a given day) is unique, and combined with the -----
----- (b)(4)-----, allows exact identification of the assay run. Please clarify if other parameters should be considered.

Because an assay run will be identified uniquely based on the "(b)(4)" and ----- (b)(4)-----, we don't need to consider other parameters.

Item 15

We believe this item refers to the subjects that withdrew or prematurely discontinued the study due to an SAE or AE. We kindly request that CBER confirm our interpretation or clarify the request.

We are referring to the 11 subjects (10 Hib-MenCY-TT and 1 Hib) who withdrew or prematurely discontinued the study due to SAEs or AEs.

Item 84

Item 84 includes the statement "You have not provided information showing that the technicians who performed the assays for this study were capable of providing consistent (b)(4) readings". Please clarify if this statement relates to blinding of the samples (part b of Item 4). If not, please clarify what information is needed regarding technicians performing this assay.

Yes. Our statement relates to part b of Item 84 "Please provide information regarding whether the clinical samples were handled in a blinded manner when using -(b)(4)- to detect anti-VZV antibody, and how many technicians were

directly involved in the analysis of samples by (b)(4)." Records showing that the technicians who were directly involved in the analysis of the clinical samples by (b)(4) were successfully trained will also be helpful.

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