

# Record of Telephone Conversation - May 19, 2009 - Hiberix

Submission Type: Original Application Submission ID: 125347/0 Office: OVRR

Product: Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) "Hiberix"

Applicant: GlaxoSmithKline Biologicals

Telecon Date/Time: 19-MAY-2009 10:30 AM

Initiated by FDA? Yes

Communication Category: Information Request

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Telecon Summary:

Request for SOPs, reagents and the required samples for testing in-support for BLA.

## **FDA Participants:**

Jay Slater, M.D.

Jennifer Bridgewater, MPH

Mustafa Akkoyunlu, Ph.D., M.D.

Scott Norris

Jason Humbert

Tina Roecklein

Karen Campbell

Rajesh Gupta, Ph.D.

Alfred Del-Grosso, Ph.D.

James Kenney, Ph.D.

Manju Joshi, Ph.D.

## **Non-FDA Participants:**

Diana Dominguez, Technical Regulatory Affairs

Veronique Goffin, QC Biochemistry

Jody Gould, Director, Vaccines, North American Regulatory Affairs

Elisa Harkins, Associate Director, Vaccines, North American Regulatory Affairs

Cecile Ponsar, Director, Manufacturing ----b(4)----- Vaccines

Norris Pyle, Assistant Director, Vaccines, North American Regulatory Affairs

Marianne Verbois, QC Physical Chemistry

-b(6)---, Manufacturing ----b(4)----- Vaccines

Terry Ward, Sr. Director, Vaccines Establishment, North American Regulatory Affairs

## **Telecon Body:**

This meeting was held to discuss the information request of May 11, 2009 (see telecon record) regarding SOPs, samples and reagents.

Dr. Slater began by stating that the purpose of the meeting is to go through the SOPs in question and discuss minor clarifications requested by CBER. More substantive comments will be forthcoming in a formal Information Request. Dr. Gupta asked if the SOPs had been tailored to U.S. regulatory standards. GSK stated that indeed the SOPs have been translated and modified to accommodate U.S. review. In particular, several SOPs were discussed:

- SOP 9000010114 (sections 5.4.2.2, and 5.5.7.1). GSK will address CBER's clarification requests discussed during this teleconference by either incorporating the information

directly into the SOPs or by providing the clarifications via writing to CBER as agreed during the teleconference. GSK is expecting to be able to file this amendment within two weeks.

GSK stated that they are targeting May 27th to ship the reagents and samples not received by CBER. They further stated that the 0.9% sodium chloride being provided will be manufactured by GSK, as opposed to -----b(4)----- as indicated in the original application. GSK stated that in the interest of time and since no 0.9% sodium chloride diluent is currently available from -b(4)-, GSK 0.9% sodium chloride diluent is being provided. GSK stated their manufactured diluent meets the same acceptance criteria, and a copy of the CoA will be included in the shipment to CBER. For the compendial methods, GSK is obtaining method verification reports. GSK is expecting to have this information available in the next two weeks.

Regarding the --b(4)---- Test in Drug Substance, GSK clarified that the Hib drug substance is considered equivalent to -b(4)- for conducting this test, and that total -b(4)- content was being tested. The discussion then turned to GSK's plans to perform this test itself post-approval. CBER stated that they would like to see this change (GSK being added as a testing site for the -b(4)- test on drug substance) reported as a PAS and GSK agreed.

The following were identified as action items:

1. GSK will obtain information on the reagent and sample shipments (including the invoice number, contents, and tracking number) and notify CBER when the shipment occurs so as to facilitate receipt of these items.
2. GSK will ensure GSK 0.9% sodium chloride diluent conforms to the same filed acceptance criteria as the -b(4)- 0.9% sodium chloride diluent, and the CoA is included in the shipment.
3. The method validation protocols and reports, the method verification reports, and the clarified SOPs (SOP 9000010114, SOP 90000010221, and SOP 9000006115) will all be available for official submission to the BLA in approximately two weeks. GSK will notify CBER when they are submitted.

Call concluded.