

Record of Telephone Conversation, February 6, 2012 - MenHibrix

Submission Type: BLA

Submission ID: 125363/0

Office: OVRP Product:

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

Applicant: GlaxoSmithKline Biologicals

Telecon Date/Time: 06-Feb-2012 04:00 PM

Initiated by FDA? Yes

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

Communication Category(ies):

1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary: Reagent/Documentation Request

FDA Participants: KIRK PRUTZMAN

Non-FDA Participants: JODY GOULD Trans-BLA Group: No

Related STNs: None

Related PMCs: None Telecon Body:

Hi Jody,

By Kirk Prutzman at 4:10 pm, Feb 06, 2012

Please find attached a spreadsheet that contains a list of Reagents and Documentation requested by our product quality reviewers. The documentation can be emailed directly to Karen Campbell (Karen.Campbell@fda.hhs.gov). It does not need to be sent to the BLA.

Please contact Karen Campbell when reagents are sent. Please send reagents to:

Karen Campbell

Regulatory Coordinator

Division of Biological Standards and Quality Control (DBSQC) OCBQ/CBER/FDA HFM-680

5516 Nicholson Lane

Kensington, MD 20895 office (301)594-6255

Regards,

Kirk Prutzman, PhD

Food and Drug Administration

Primary Reviewer/Regulatory Project Manager

CBER/OVRP/DVRPA/CMC3

1451 Rockville Pike (WOC2) Room 2241

HFM-481

Rockville, MD 20857

Phone: (301) 796-2640

Reagents for MenHiberix Drug Product Testing 1/20/2012

If available, please send qualification reports for all reagents, these are needed for the labs performing the testing. Analytical Chemistry Staff -----(b)(4)-----

-(b)(4)- Determination of Individual Polysaccharide in Final Container Hib Men CY by ----(b)(4)-----

----(b)(4)-----	----(b)(4)-----	VERIFY
---(b)(4)---	---(b)(4)---	VERIFY
---(b)(4)-----	---(b)(4)---	VERIFY
---(b)(4)-----	---(b)(4)-----	NEED
---(b)(4)-----	---(b)(4)-----	NEED

Hib Type B:Detn. Of molecular distribution of HIB in the combs HIB Men CY by ----

(b)(4)-----	---(b)(4)---	---(b)(4)---	NEED	---(b)(4)---
(b)(4)-----	VERIFY	---(b)(4)---	---(b)(4)---	VERIFY
---(b)(4)---	---(b)(4)---	NEED	---(b)(4)---	---
(b)(4)-----	NEED	---(b)(4)---	---(b)(4)---	VERIFY -
---(b)(4)---				

Determination of the PSC and PSY content in Final Containers by ----(b)(4)-----

----(b)(4)-----	----(b)(4)-----	NEED
	----(b)(4)-----	NEED
----(b)(4)-----	----(b)(4)-----	NEED

Determination of the Polysaccharide Content in HIB Vaccine by ----(b)(4)-----

----(b)(4)-----	----(b)(4)-----	VERIFY
---(b)(4)---	---(b)(4)---	VERIFY

NEED - used up or unable to locate this material

VERIFY - Have stock, but need verification of suitability due to lack of expiration date

Identity Testing by ---(b)(4)---

Hib-TT ---(b)(4)--- Lot#

Recommended Dilution/reconstitution volume

---(b)(4)---	---(b)(4)---	---(b)(4)---	VERIFY
---(b)(4)---	---(b)(4)---	---(b)(4)---	
VERIFY			
---(b)(4)---			
---(b)(4)---	---(b)(4)---	---(b)(4)---	VERIFY

PSC- and PSY-TT ---(b)(4)---

----(b)(4)-----	----(b)(4)-----	--(b)(4)--	VERIFY
---(b)(4)---	---(b)(4)---	--(b)(4)--	VERIFY
---(b)(4)---	---(b)(4)---	--(b)(4)--	VERIFY
---(b)(4)---			
---(b)(4)---	---(b)(4)---	--(b)(4)--	VERIFY
---(b)(4)---			
---(b)(4)---	---(b)(4)---	--(b)(4)--	VERIFY

VERIFY - Have stock, but need verification of suitability due to lack of expiration date

If the reagents have been requalified please send documentation and any changes to the recommended dilutions.