

# Record of Telephone Conversation, June 6, 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: 06-Jun-2011 10:30 AM Initiated by FDA? Yes  
Telephone Number: norris.h.pyle@gsk.com, jody.a.gould@gsk.com  
Communication Category(ies):  
1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary:

Request for Samples, Reagents and Documentation required for testing

FDA Participants: KIRK PRUTZMAN, JOSEPH TEMENAK, DAVID STATEN,  
JENNIFER BRIDGEWATER, TINA ROCKLEIN

Non-FDA Participants: JODY GOULD, NORRIS PYLE

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Dear Dr. Pyle and Dr. Gould:

Regarding our meeting on May 26, 2011, we have the following request for Samples, Reagents and Documentation required for testing.

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

June 2011 STN 125363

Request for Samples, Reagents and Documentation required for testing

I. Samples

Drug Product (final container) – 3 different lots – -b(4)- containers each

Drug Substance (individual conjugates) – For each conjugate, ----b(4)-----  
of each.

II. Reagents

If sending reagents, please send enough for –b(4)- tests.  
Please resend enough reagents and materials for b(4) tests for each of the following tests

**DRUG SUBSTANCE PROCEDURES**

**Hib-TT**

-----b(4)-----  
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**MenC-TT**

-----b(4)-----  
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**MenY-TT**

-----b(4)-----  
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**DRUG PRODUCT PROCEDURES**

-----b(4)-----  
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III. Documentation

For all reagents to be sent or already received please send expiration dates and qualification reports.

We received the following reagents for Identity Testing by –b(4)--, we need expiration dates and qualification reports. If any are past their expiration date, please send new or documentation to support extending the expiration date. Please indicate if there is any change to the dilution for any reagents, if they have been requalified., otherwise we have enough for now.

**Identity Testing by –b(4)---**

<b>Hib-TT—b(4)---</b>	<b>Lot #</b>
1) --b(4)-----	--b(4)-----
2)Standard	--b(4)-----
3) -----b(4)-----	--b(4)-----
<b>PSC- and PSY-TT –b(4)---</b>	
--b(4)-----	-----b(4)-----
--b(4)-----	--b(4)-----
--b(4)-----	--
--b(4)-----	--b(4)-----
--	--b(4)-----
--b(4)-----	--b(4)-----

