

RECORD OF TELEPHONE CONVERSATION

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: 16-Jun-2011 11:04 AM Initiated by FDA? No

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Communication Category(ies):

1. Other -

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Telecon Summary:

GSK's Response to our 5-26-2011 request for samples, reagents and documentation

FDA Participants: KIRK PRUTZMAN, JOSEPH TEMENAK, DAVID STATEN

Non-FDA Participants: NORRIS PYLE, JODY GOULD

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Hello everyone,

I received the email from Dr. Prutzman on June 6, and GSK is in the process of responding to the request.

Please find below information regarding the remaining action items from the May 26, 2011 teleconference. Please feel free to contact me either by email or by telephone (610-689-0709) with any questions, comments or requests.

Thank you - Norris

1. GSK to identify when additional bulk conjugate lots are planned for production and provide details on when samples can be provided to CBER. (samples from b(4) lots of each of the three conjugates are being requested)

2. There would also be differences in the testing performed. The COAs would have “ex-US” test results.

Specifically, the free PS test method ex-US is an –b(4)- test versus the b(4) method which determines free MenC content by –b(4)----- . GSK has proposed the use of a –b(4)----- in place of the –b(4)----- as it is more accurate as the –b(4)----- test can detect smaller sized free PS. Also, –b(4)----- is -----b(4)-. Per the April 15, 2011 complete response (Question 37) GSK has outlined that –b(4)- will be performed via the new b(4) method using ---b(4)----- ----- as of March 15, 2011.

Would the use of these two representative “ex-US” lots be acceptable to CBER? Would CBER request that GSK perform testing on the “ex-US” lots per the MenHibrix BLA and provide results?

Samples of bulk conjugate lots already manufactured can be provided with the re-supply of expired reagents currently being scheduled to be provided to CBER. Samples of lots being produced in July would be provided to CBER by the end of September.

Note that GSK can provide CBER with –b(4)----- and corresponding reagents for the new –b(4)--- (please see GSK’s response to Question 37 in the April 15, 2011 complete response submission). Please let me know how many –b(4)-----s would be sufficient.

2. GSK to provide CBER with information as to when samples of the new launch lots will be provided, and how many lots this will be.

Note that the final container lots received to date are 2 years old and are within the proposed 3 year shelf life. b(4) additional final container lot is scheduled to be manufactured in August 2011, and b(4) additional final container lots, pending BLA approval, will be manufactured in November 2011. Samples for the August lot will be provided to CBER for lot release by the end of October, and samples of the November lots, if manufactured, would be provided to CBER for lot release by the end of January.

3. GSK to provide CBER with an estimate of how many commercial lots would need to be released per year.

The answer to this question is dependent on ACIP recommendations. If ACIP recommends permissive use, GSK currently forecasts the following in terms of lots per year:

2012: b(4) batches (based upon forecast of --b(4)-- doses)
2013: b(4) batches (based upon forecast of --b(4)-- doses)
2014: b(4) batches (based upon forecast of --b(4)-- doses)

GSK is currently assessing the forecast if ACIP recommends high risk use. The numbers would be lower than if ACIP recommends permissive use.