

Meeting Summary, June 14 2012 -Q-Pan

- **Date and Time:**

June 14, 2012, 11:00 AM – 12:30 PM

Location:

WOC2 – Room 2330

STN #:

125419/0

Sponsor:

GlaxoSmithKline Biologicals

Product:

Influenza A (H5N1) Virus Monovalent Vaccine

CBER/FDA PARTICIPANTS

COMMITTEE MEMBERS

Review Assignment	Committee Member	Supervisor
Chair	Carmen Collazo-Custodio	Elizabeth Sutkowski
Lead RPM	Jeremy Wally	Elizabeth Sutkowski
Co-RPM	Kirk Prutzman	Elizabeth Sutkowski
Product CMC	Hana Golding	Jerry Weir
Product CMC	Surender Khurana	Hana Golding
Product Quality	Manju Joshi	William McCormick
Product Quality	Lokesh Bhattacharyya	William McCormick

Review Assignment

Committee Member

Supervisor

Product Quality

Karen Campbell

William McCormick

OTHER ATTENDEES

Anissa Cheung

Alfred Del-Grosso

Hyesuk Kong

William McCormick

Catherine Poole

Muhammad Shahabuddin

Elizabeth Sutkowski

1.0

PURPOSE

This meeting was held todiscuss testing of the Q-Pan H5N1 vaccine.

2.0

DISCUSSION TOPICS

2.1

Testing of Influenza A (H5N1) Virus Monovalent Vaccine - Testing in-support

2.1.1

The following tests will be conducted on the Influenza A (H5N1) Virus Monovalent Vaccine Lots (final container lots):

- Sterility (Jim Kenney)
- (b)(4) (Hyesuk Kong)
- Identity/Potency (Manju Joshi)
- Thimerosal content (Alfred Del-Grosso)
- Formaldehyde content (Alfred Del-Grosso)

2.1.2

Karen Campbell and Carmen Collazo-Custodio will fill out forms **PRB-101**: (Request for Control Tests) and **PRB-201** (LAB Sample Request) and submit to the Product Release Branch to request samples to be delivered to the testing labs.

Lot numbert

Sample Quantity/Volume

Lot number	Sample Quantity/Volume
---(b)(4)-----	(b)(4) x 2.5 mL/vial (10 mL vial size)
---(b)(4)-----	(b)(4) x 2.5 mL/vial
---(b)(4)-----	(b)(4) x 2.5 mL/vial

2.1.3

Reviewers need to search in the application to confirm that the antimicrobial effectiveness testing data were submitted to support the reduced preservative formulation of the Q-Pan H5N1 vaccine.

2.2

Testing of AS03 Adjuvant - Testing in-support

2.2.2

The following tests will be conducted on the AS03 adjuvant:

- ---(b)(4)----
- -----(b)(4)-----
- α -tocopherol (identity and content) by (b)(4)
- Squalene (identity and content) by (b)(4)

2.2.3

CBER will request adjuvant samples from GSK (final container lots).

2.2.4

CBER will inquire about how the adjuvant is going to be stored in the Strategic National Stockpile (reviewers will search in the application to find out if this information was provided).

2.3

Potency Testing of Influenza A (H5N1) Virus Monovalent Vaccine (monovalent (b)(4) samples submitted to Karen Campbell)

2.3.1

Manju Joshi is working on the potency testing. An initial screening is being conducted to assess the new potency reagents.

2.3.2

CBER will request the Excel spreadsheet GSK uses for the SRID calculations.

2.4

Lot Release Protocol

2.4.1

Lot Release Protocol of the Influenza A (H5N1) Virus Monovalent Vaccine Bulk will be based on *FluLaval*, the influenza virus seasonal vaccine.

2.4.2

Lot Release Protocol of the AS03 adjuvant is to be determined (if decided that a Lot Release Protocol for the adjuvant will be developed). Possible tests are -----(b)(4)----- for α -tocopherol and squalene identity and content.

2.4.3

Final testing will be determined as the BLA review progresses.

2.4.4

CBER will request a Lot Release Protocol from GSK (we could provide a draft template).

2.4.5

An additional meeting will be convened after the “in-support testing” has been completed. Additional discussion is also pending once the applicant submits the Lot Release Protocol and CBER has the opportunity to review it.

2.5

Lot Release Testing Plan

2.5.1

The following questions need to be answered during the development of the testing plan:

- Are the testing requirements, including the methods to be used, adequately defined, documented and understood?
- Does the laboratory have the capability and resources to meet the requirements?
- Has the appropriate test method been selected? Is the test method capable of meeting the requirements of the product release program specified by the product office in the testing plan?

Answers to these questions will be provided as the testing procedures are developed.

2.5.2

A Product Testing Plan Draft should be prepared by Mid Cycle Meeting (July 20, 2012).

2.6

Exemption from General Safety Testing (GST)

2.6.1

GSK requested exemptions from the GST for both the Quebec H5N1 antigen and the AS03 adjuvant.

2.6.2

In support of this request, they provided data on (b)(4) lots for AS03 adjuvant and (b)(4) lots for Quebec H5N1 antigen.

2.6.3

CBER will evaluate the testing history of this request and provide a final recommendation based on this assessment.

3.0

ACTION ITEMS

Action item

Owner

1. Fill out forms **PRB-101**: (Request for Control Tests) and **PRB-201**

Karen Campbell and

Action item**Owner**

(LAB Sample Request) and submit to the Product Release Branch to request samples of the final container lots of the Quebec H5N1 antigen

Carmen Collazo-Custodio

2. Search in the application to confirm that the antimicrobial effectiveness testing data were submitted to support the reduced preservative formulation of Q-Pan H5N1.

Hana Golding, Surender Khurana and Carmen Collazo-Custodio

3. Request adjuvant samples (final container) from GSK

Karen Campbell and Carmen Collazo-Custodio

4. Find out how the adjuvant is going to be stored in the Strategic National Stockpile (search in the application to find out if this information was provided)

Carmen Collazo-Custodio

5. Testing of the Influenza A (H5N1) Virus Monovalent Vaccine Lots

Refer to Section 2.1.1, above

6. Potency testing of H5N1 -----(b)(4)-----

Manju Joshi (refer to Section 2.3, above)

7. Request Excel spreadsheet GSK uses for the SRID calculations

Carmen Collazo-Custodio (as part of an Information request)

8. Request a Lot Release Protocol from GSK

To be determined

4.0

ACTION ITEMS UPDATE

Item 1: Forms were submitted to Cheryl Hulme (Product Release Branch) on June 19, 2012.

Items 2 and 4: Information below obtained from e-mail correspondence from Dr. Michael Schwartz (GSK) to Dr. Carmen Collazo-Custodio (CBER), dated June 15, 2012:

Item 2- location of the antimicrobial effectiveness testing data

This information is located in section P.2.5 Microbiological Attributes. Refer to section 3.2.P.2.5 in the antigen section and the 3.2.P.2.5 in the combo section.

Item 4- In the BLA GSK doesnot specifically state how the adjuvant and antigen are stored in the Strategic National Stockpile. With regards to antigen, the stockpile consists of -----(b)(4)----- stored in -----(b)(4)---- and final container drug product stored in vials (small quantity), both at 2-8° C. These storage conditions are in-line with what is described in the BLA. With regards to adjuvant, the stockpile consists of formulated (b)(4) drug product stored --- (b)(4)-- and filled drug product stored in final container vials, both at 2-8° C. Final container drug product storage is in-line with what is in the BLA. Formulated (b)(4) drug product storage - (b)(4)- is not contained within the BLA, but GSK plans to submit a supplement for its use after approval of the BLA.

Items 3 and 7: Request submitted on June 21, 2012. CBER requested (b)(4) vials (10 mL vials/2.5 mL sample) from 3 final container lots of the AS03 adjuvant to be shipped to Karen Campbell.