

**MEETING SUMMARY**

<b>Date and Time:</b>	October 5, 2012 1:30 pm – 2:30 pm
<b>Location:</b>	WOC2 – Room 2330
<b>STN #:</b>	125419/0
<b>Sponsor:</b>	ID Biomedical Corporation of Quebec (dba GlaxoSmithKline Biologicals)
<b>Product:</b>	Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

**CBER/FDA Invitees**

<b>Attended</b>	<b>Committee Member</b>	<b>Review Assignment</b>	<b>Supervisor</b>
✓	Carmen Collazo-Custodio	Chair	Elizabeth Sutkowski
✓	Jeremy Wally	Lead RPM	Elizabeth Sutkowski
✓	Kirk Prutzman	Co-RPM	Elizabeth Sutkowski
✓	Andrea James	Clinical	Lewis Schrager
✓	Hana Golding	Product CMC	Jerry Weir
✓	Surender Khurana	Product CMC	Hana Golding
	Nabil Al-Humadi	Toxicology	David Green
✓	Tsai-Lien Lin	Clinical/Assay Stats	Dale Horne
✓	Tielin Qin	Assays Stats	Dale Horne
✓	Maryann Gallagher	Advertising/Promotional Labeling	Lisa Stockbridge
✓	Cheryl Hulme	Lot Release	Joseph Quander III
✓	Yandong Qiang	Pharmacovigilance	Wei Hua
✓	Hector Izurieta	Epidemiology (Effectiveness)	Richard Forshee
✓	Anthony Hawkins	BIMO	Patricia Holobaugh
	Randa Melhem	Facilities/DMPQ	Chiang Syin
	Jei He	Facilities/DMPQ	Chiang Syin
	James Kenney	Product Quality	Rajesh Gupta
✓	Manju Joshi	Product Quality	William McCormick
✓	Lokesh Bhattacharyya	Product Quality	William McCormick
✓	Karen Campbell	Product Quality	William McCormick
	David Schwab	Electronic Integrity Review	Laraine Henschel

**OTHER ATTENDEES:**

Elizabeth Sutkowski	William McCormick
Lewis Schrager	Wellington Sun
Richard Forshee	

## 1.0 PURPOSE

The objectives of this meeting were:

- A. To update Management on the review progress
- B. To update the review team on upcoming items including VRBPAC and the Final Review Deadline

## 2.0 BACKGROUND

The proposed indication of BLA STN 125419 is for active immunization for the prevention of disease in persons 18 years of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.

## 3.0 DISCUSSION TOPICS

### 3.1 Milestones and Meetings

<b>Milestone</b>	<b>Projected Date</b>
▪ Application Received	February 22, 2012
▪ <b>Committee Assignment</b>	<b>March 7, 2012 (FDA Tracked Milestone)</b>
▪ 1st Committee Meeting	March 12, 2012
▪ Filing Meeting	April 9, 2012
▪ Filing Letter Issued	April 22, 2012
▪ <b>1st draft reviews</b>	<b>June 21, 2012</b>
▪ <b>Mid-Cycle Review Meeting</b>	<b>July 20, 2012 (FDA Tracked Milestone)</b>
▪ <b>2<sup>nd</sup> draft reviews</b>	<b>August 30, 2012</b>
▪ <b>Final Reviews (Signed/Uploaded)</b>	<b>October 14, 2012</b>
▪ Present to PeRC	September 26, 2012
▪ <b>Labeling Comments to Sponsor</b>	<b>November 9, 2012 (FDA Tracked Milestone)</b>
▪ Notify GSK of PMC/PMR	November 12, 2012
▪ Labeling Complete	December 4, 2012
▪ <b>First Action Due</b>	<b>December 22, 2012</b>

### Meetings

First Committee Meeting:	March 6, 2012
Filing Meeting:	April 9, 2012
Monthly Team Meetings:	May 8, 2012
	June 11, 2012
	July 9, 2012
	August 3, 2012 (revised date)
	August 31, 2012 (revised date – Sept. Meeting)

**October 5, 2012 (revised date)**  
November 6, 2012 (revised date)  
December 10, 2012

<b>Mid-Cycle Review Meeting:</b>	<b>July 20, 2012</b>
PeRC:	September 26, 2012
VRBPAC:	November 14
SWG:	Not Scheduled
Labeling Meetings:	October 9, 2012 & October 12, 2012

### **3.2 Team Reports:**

#### **3.1 Chair**

The chair reminded the review committee that the deadline for final reviews to be signed and uploaded to the EDR was October 14, 2012. All reviews needed to include the correct name of the sponsor [ID Biomedical Corporation of Quebec (dba GlaxoSmithKline Biologicals)] and the revised name of the proper name of the product [Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted]. Reviewers who would not be able to finalize their reviews by the October 14, 2012, deadline were instructed to document the reason for the delay in an e-mail to the chair and RPMs.

#### **3.2 Clinical**

Clinical reported that the review was ongoing and that one information request to GSK may be forthcoming. Clinical also reported that they were preparing for the November 14, 2012, VRBPAC.

#### **3.3 Statistical**

Statistics reported that their reviews were being finalized and also reported an issue that has arisen with product stability. The (b)(4) month stability for the vaccine was failing using a common slope analysis. Statistics and CMC reviewers were going to discuss this issue further after the meeting. An information request or telecon with GSK to discuss this issue may be forthcoming.

#### **3.4 CMC/Product**

The CMC reviewers reported that their reviews were being finalized.

#### **3.5 Toxicology**

The Toxicology review was completed and uploaded to the EDR.

### 3.6 Facilities/DMPQ

No Report

### 3.7 Epidemiology (Effectiveness Study)

The Epidemiology (Effectiveness Study) review was completed and uploaded to the EDR.

### 3.8 BIMO

The BIMO review was completed and uploaded to the EDR.

### 3.9 Pharmacovigilance

Pharmacovigilance reported that the review was ongoing and that there was one outstanding information request item that needed to be addressed by GSK. Pharmacovigilance also reported that they were considering whether any PMCs would be requested. They also indicated that would need a statistics safety review.

### 3.10 Lot Release

Lot Release reported that they were waiting for GSK to respond to several information request items. The Product Testing Plan will be finalized after the Lot Release Protocol is finalized.

### 3.11 APLB

APBL reported that their review was being finalized.

#### 4.0 Information Requests / Amendments

Request Date	CBER Rep(s)	Request	CBER Requester for Info	BLA Amendment Response	Review Pending?	Reviewed by and Date Reviewed
4/30/2012a	Carmen Collazo-Custodio	IR for Pediatric Plan, stability data, clinical assay validation, HA content by SRID validation, other assay validation, facilities information, pharmacovigilance	Andrea James, Hana Golding, Surender Khurana, Tsai-Lien Lin, Tielin Qin, Manju Joshi Lokesh Bhattacharyya, Yandong Qiang, Randa Melhem	125419.3 125419.4 125419.5	Yes	
4/30/2012b	Carmen Collazo-Custodio	Revised 356h form, SRID testing reagents and results	Carmen Collazo, Karen Campbell	125419.1 125419.2	Yes	
6/21/2012	Carmen Collazo-Custodio	Adjuvant lots and SRID calculation spreadsheet	Karen Campbell	-	-	
7/30/2012	Carmen Collazo-Custodio	Product Manufacturing Questions	James Kenney, Hyesuk Kong, Karen Campbell, Surender Khurana, Randa Melhem	125419.6 125419.9 125419.10	Yes	
8/10/2012	Kirk Prutzman	AS03 Manufacturing Quality	Randa Melhem	125419.8	Yes	
8/15/2012	Kirk Prutzman	Follow questions to GSK's responses to questions 16, 17d, 18, 21, 22 from the 4/30/2012 IR	Lokesh Bhattacharyya		Yes	
8/16/2012	Carmen Collazo-Custodio	IR Regarding GSK's SRID Results	Manju Joshi, Rajesh Gupta, Karen Campbell	125419.7 125419.10	Yes	
8/25/2012	Jeremy Wally	IR regarding SRID assay and additional comments on VRBPAC and Proper Name	Manju Joshi Carmen Collazo-Custodio	125419.10	Yes	
8/26/2012	Carmen Collazo-Custodio	IR regarding Pharmacovigilance Plan	Yandong Qiang		Yes	
10/2/2012	Kirk Prutzman	IR for qualification test reports for the AS03 Adjuvant	James Kenney		Yes	

#### Amendments

Date/STN	Summary
May 3, 2012 (125419.1)	Partial response to 4/30/2012b IR. Revised 356h form.
May 25, 2012 (125419.2)	Partial response to 4/30/2012b IR. Answers to Item 2.
June 20, 2012 (125419.3)	Partial response to 4/30/2012a IR. Answers to Items 24-34.
July 18, 2012 (125419.4)	Partial response to 4/30/2012a IR. Answers to Items 2-23 and 35-36.

July 19, 2012 (125419.5)	Partial response to 4/30/2012a IR. Answer to Item 1. All responses to IR now submitted.
August 13, 2012 (125419.6)	Partial response to 7/30/2012 IR. Answer to Item 1. Addition of Robert D. Brobst as secondary POC
August 29, 2012 (125419.7)	Response to 8/16/2012 tcon; updated 356h form; updated list of POC's.
September 10, 2012 (125419.8)	Response to 8/10/2012 tcon
September 14, 2012 (125419.9)	Response to Questions 2, 3, and 5-18 from CBER's 7/30/2012 IR.
September 28, 2012 (125419.10)	Response to Information Requests dated July 30, 2012, August 16, 2012, and September 25, 2012.