

**MEETING SUMMARY**

<b>Date and Time:</b>	November 6, 2012 12:30 pm – 1:30 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  
Erik Henschel  
William McCormick  
Lewis Schrager

## 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
- C. To discuss remaining topics that needed to be addressed before the Action Due Date

## 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)

<b>Mid-Cycle Review Meeting:</b>	<b>July 20, 2012</b>
PeRC:	September 26, 2012
VRBPAC:	November 14
SWG:	Not Scheduled
Labeling Meetings:	October 22, 2012, October 25, 2012, November 2, 2012

### 3.2 Team Reports:

### 3.1 Chair

The Chair reminded the review committee of the deadlines (above) and instructed the committee to be sure that their reviews were complete before they are uploaded to the EDR. There were several outstanding information requests (IRs) at the time of the meeting; thus it was important to emphasize that the final reviews uploaded to the EDR should address all the IRs (i.e., to include the amendment number and the date of submission) and provide an assessment of the adequacy of GSK's response.

### 3.2 Clinical

The Clinical reviewer was waiting for GSK's response to 2 outstanding IRs. There were no other issues that would delay completion of the clinical review. There were no PMCs to report.

### 3.3 Statistical

The Statistical reviewers reported that IR comments were being drafted regarding a lower limit of (b)(4) for the SRID assay used for potency measurement.

### 3.4 CMC/Product

The CMC reviewers were waiting for GSK's response to outstanding IRs. There were no PMCs to report.

### 3.5 Facilities/DMPQ

[illegible]

### 3.6 Pharmacovigilance:

The Pharmacovigilance reviewer was waiting for GSK's response to 2 outstanding IR comments. There were no PMCs to report.

### 3.7 DBSQC and Lot Release

The Lot Release reviewers reported that the Lot Release Protocol (LRP) was being finalized. Testing in support (including AS03 sterility testing) was ongoing. Regarding the samples that failed the SRID test, GSK explained that they were from expired lots. The reviewer will prepare an addendum to an earlier memo to explain that the reason for failing the SRID test was because the lots had expired.

### 3.8 Toxicology

#### 3.8.1 Review Uploaded to EDR

### 3.9 Epidemiology (Effectiveness Study)

#### 3.9.1 Review Uploaded to EDR

### 3.10 BIMO

#### 3.10.1 Review Uploaded to EDR

### 3.11 APLB

#### 3.11.1 Review Uploaded to EDR

### 3.12 Other Disciplines

## 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 125419.11	Yes	Surender Khurana – 125419.4 Hana Golding – 125419.4
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	Surender Khurana – 125419.9 125419.10
8/10/2012	Kirk Prutzman	AS03 Manufacturing Quality	Randa Melhem	125419.8	Yes	
8/15/2012	Kirk Prutzman	Follow questions to GSK's	Lokesh	125419.11	Yes	

Request Date	CBER Rep(s)	Request	CBER Requester for Info	BLA Amendment Response	Review Pending ?	Reviewed by and Date Reviewed
		responses to questions 16, 17d, 18, 21, 22 from the 4/30/2012 IR	Bhattacharyya			
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	125419.12	Yes	
10/10/2012	Carmen Collazo-Custodio	IR regarding the PVP	Yandong Qiang		Yes	
10/15/2012	Kirk Prutzman	IR Regarding Clinical Items	Andrea James		Yes	
10/16/2012	Carmen Collazo	IR Regarding Lot Release Protocol	Karen Campbell	125419.13	Yes	
10/17/2012	Carmen Collazo	IR comments: clinical (subgroup analyses) and clarification on filling of AS03 (-----)(b)(4)----- )	Andrea James			
10/18/2012	Kirk Prutzman	IR Regarding Anti-Microbial Effectiveness Testing	James Kenney		Yes	
10/22/2012	Carmen Collazo	IR comment on GSK's PVP	Yangdong Qiang		Yes	
10/31/2012	Carmen Collazo	Request for CRFs for subjects in study Q-Pan-002	Andrea James		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 (facilities).
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	Response to 8/10/2012 tcon

(125419.8)	
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.
October 10, 2012 (125419.11)	Response to Information Requests dated April 30, 2012, and August 15, 2012.
October 18, 2012 (125419.12)	Response to IR from CBER dated October 2, 2012
October 26, 2012 (125419.13)	Response to IR from CBER dated October 16, 2012 regarding the LRP