

**MEETING SUMMARY**

Date and Time:	August 31, 2012 1:30 pm – 2:30 pm
Location:	WOC2 – Room 2330
STN #:	125419/0
Sponsor:	ID Biomedical Corporation of Quebec (dba GlaxoSmithKline Biologicals)
Product:	Influenza A (H5N1) Virus Monovalent Vaccine
Meeting Recorders:	Jeremy Wally, Kirk Prutzman

CBER/FDA Invitees**CBER/FDA INVITEES****COMMITTEE MEMBERS:**

Attended	Committee Member	Review Assignment	Supervisor
✓	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
		Advertising/	
	Maryann Gallagher	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
✓	Manju Joshi	Product Quality	William McCormick
✓	Lokesh Bhattacharyya	Product Quality	William McCormick
✓	Karen Campbell	Product Quality	William McCormick
	David Schwab	Electronic Integrity Review	Laraine Henchal

OTHER ATTENDEES:

James Kenny	Elizabeth Sutkowski	Lewis Schrager
John Eltermann	Richard Forshee	
Brenda Baldwin	Wei Hua	

1.0 PURPOSE

The objectives of this meeting are:

- 1.1 To update Management on the review progress (including 2nd Draft Review Progress)
- 1.2 To update the review team on upcoming items, including VRBPAC, PeRC, and review deadlines
- 1.3 To discuss the proper name of the product
- 1.4 To provide an update on the review of the draft lot release protocol

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

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

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

Mid-Cycle Review Meeting:

July 20, 2012

PeRC:

September 26, 2012

VRBPAC:

November 14, 2012

SWG:

Not Scheduled

Labeling Meetings:

Not Scheduled

3.2 Team Reports:

3.1 Clinical

Clinical reported that the review was ongoing and that there were no major issues identified to date. There was also a discussion about the including the adjuvant in the proper name.

3.2 Statistical

No Report

3.3 CMC/Product

Second draft reviews were completed. CMC/Product indicated that they would have additional IR comments for GSK.

3.4 Toxicology

Second draft review was completed.

3.5 Facilities/DMPQ

DMPQ discussed their issues regarding GSK's manufacture of the vaccine and adjuvant which were communicated to GSK on 8/20/2012. The DMPQ second draft review could not be completed until these issues were clarified.

DMPQ also presented the draft version of the "Review of Diluents: Overview of the Process" Tech Tips document . At the time of this meeting, DMPQ's policy was to apply the principles outlined in this document regarding the review of diluents that are used for the reconstitution of licensed biological

products to the review of adjuvants that are are packaged separately and mixed with the antigen at bedside.. As such, DMPQ's primarily regulatory concern regarding the AS03 adjuvant was ensuring sterility and that it was manufactured using cGMP.

3.6 Epidemiology (Effectiveness Study)

Second draft review was completed.

3.7 BIMO

Second draft review was completed.

3.8 Pharmacovigilance

No Report

3.9 Lot Release

No Report

3.10 APLB

No Report

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-	Product Manufacturing		125419.6	Yes	

	Custodio	Questions				
8/10/2012	Kirk Prutzman	AS03 Manufacturing Quality	Randa Melhem		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	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.