

**JUNE 2012 MONTHLY TEAM MEETING SUMMARY**

<b>Date and Time:</b>	June 11, 2012, 11:00 am – 12:00 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
<b>Meeting Chair:</b>	Carmen M. Collazo-Custodio
<b>Meeting Recorders:</b>	Kirk Prutzman and Jeremy Wally

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

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

**OTHER ATTENDEES:**

Anissa Cheung	Darlene Hithe	Erik Henchal
Wellington Sun	Wei Hua	

## 1.0 PURPOSE

The objectives of this meeting were:

- To provide an overview of outstanding items from the April 12, 2012, meeting
- To update the team on preparing 508 compliant documents - (including reviews, memos, and communications with GSK to be uploaded in the EDR)
- To update management on the status of the review of the BLA

## 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
▪ Committee Assignment	March 7, 2012 (FDA Tracked Milestone)
▪ 1st Committee Meeting	March 12, 2012
▪ <b>Filing Meeting</b>	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	October 20, 2012 (Target Date, Saturday)
▪ <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 (Saturday)</b>
<b>Meetings</b>	<b>Scheduled Date</b>
▪ <b>First Committee Meeting</b>	March 6, 2012
▪ <b>Filing Meeting</b>	April 9, 2012
▪ Monthly Team Meetings	April 30, 2012 (May Meeting; not held)
	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>Midcycle Meeting</b>	<b>July 20, 2012</b>
▪ PeRC	Not Yet Scheduled
▪ VRBPAC	Not Yet Scheduled
▪ SWG	Not Yet Scheduled
▪ Labeling Meetings:	Not Yet Scheduled

### **3.2 ACTION ITEMS FROM APRIL 9, 2012, FILING MEETING**

#### **3.2.1 An internal meeting to discuss the sponsor's request for a deferral of pediatric studies to include representatives from OVR.**

A conference call with GSK and OVR was held on May 9, 2012, to discuss this issue.

#### **3.2.2 Discussion of the Information Request comments from the Pharmacovigilance reviewer to include representatives from the clinical and statistical disciplines.**

An Information Request was sent to GSK on April 30, 2012.

#### **3.2.3 Confirmation of the decision to not conduct an inspection of the adjuvant manufacturing facility.**

A decision on this issue is still pending. Review of the sponsor's responses to comments 24 and 26-29 in the Information Request of April 30, 2012, will impact this decision.

#### **3.2.4 Discussion on testing of the adjuvant component of the vaccine to include representatives from the CMC and Product Quality teams.**

An internal meeting is scheduled for June 14, 2012 (antigen and adjuvant testing) to discuss this issue.

#### **3.2.5 The review team agreed that this BLA is filable so a Filing Letter will be drafted and sent to the sponsor.**

A No Deficiencies Identified Filing Letter was sent to GSK on April 16, 2012.

**3.2.6 Comments to be included in an Information Request have already been received from several reviewers. Once these comments have been finalized and the sponsor has received the Filing Letter, this Information Request will be communicated to the sponsor.**

An Information Request was sent to GSK on April 30, 2012.

**3.3 508 COMPLIANCE DOCUMENTS**

A discussion of the DVRPA job aid RJA-020-00 for preparing documents 508 compliant was led by Darlene Hithe.

**3.4 TEAM REPORTS**

**3.4.1 Statistical**

The Clinical/Assay Stats Reviewer provided a preliminary interpretation of the results of the Van Buynder study after initial review. A more detailed discussion of these data will be presented on July 20, 2012, during the Midcycle Meeting.

**3.4.2 BIMO**

BIMO requested four clinical investigator inspections for Protocol 110464 (FLU Q-PAN-002 PRI) on April 19, 2012, with a requested inspection completion date of July 10, 2012. Presently, one inspection is completed (no FDA Form 483 issued). BIMO will inform the committee about the results for all requested inspections when they receive and review the corresponding inspection reports.

**3.5 MIDCYCLE MEETING**

The Midcycle meeting will be held on July 20, 2012. A preparation meeting is scheduled for July 9, 2012.

### 3.6 FIRST DRAFT REVIEWS

The first draft of review memos are due to supervisors on June 20, 2012. Milestones for the review schedule are in the Project Schedule.

### 4.0 INFORMATION REQUESTS

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 Josh,i Lokesh Bhattacharyya, Yandong Qiang, Randa Melhem	125419.2	Yes	
4/30/2012b	Carmen Collazo-Custodio	Revised 356h form, SRID testing reagents and results	Carmen Collazo, Karen Campbell	125419.1	Yes	

### 5.0 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.

### 6.0 ACTION ITEMS

- Contact GSK to request an update on the status of their responses to the Information Request of April 30, 2012.
- Review team members need to send the first draft of their review memos to their supervisors (and cc Carmen, Kirk and Jeremy) by June 21, 2012.
- An internal meeting to discuss testing of the antigen and adjuvant components of the vaccine will be held on June 14, 2012.
- An internal meeting to prepare for the Midcycle meeting will be held on July 9, 2012.