

**JULY 2012 MONTHLY TEAM MEETING SUMMARY**

<b>Date and Time:</b>	July 9, 2012, 11:00 AM – 12:00 PM
<b>Location:</b>	WOC2 – Room 2330
<b>STN #:</b>	125419/0
<b>Applicant:</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 Recorder:</b>	Kirk Prutzman

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

**OTHER ATTENDEES:**

Erik Henschel	Richard Forshee
Elizabeth Sutkowski	William McCormick
Lisa Stockbridge	

## 1.0 PURPOSE

The objectives of this meeting were:

- To have committee members provide updates on the status of their reviews
- To update the team on the status of submissions and pending review items
- To be informed of any issues identified by review team members that need to be reported to OVRM management during the Mid Cycle Meeting

## 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)

Meetings	Scheduled Date
▪ Monthly Meetings (cont)	December 10, 2012
▪ <b>Midcycle Meeting</b>	<b>July 20, 2012</b>
▪ PeRC	September 26, 2012
▪ VRBPAC	Not Yet Scheduled
▪ SWG	Not Yet Scheduled
▪ Labeling Meetings:	Not Yet Scheduled

### **3.2 ACTION ITEMS FROM JUNE 11, 2012, MEETING**

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

A conference call with GSK and OVRP was held on June 29, 2012 to discuss this issue. A submission from the sponsor was anticipated.

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

A decision on this issue was pending. The applicant's responses to comments 24 and 26-29 in the Information Request of April 30, 2012, that impact this decision, were received on June 20, 2012, in amendment 125419.3.

#### **3.2.4 Follow-up discussion regarding testing of the antigen and adjuvant component of the vaccine (meeting held on June 14, 2012)**

Lots of adjuvant and the Excel spreadsheet the applicant uses for the SRID calculation were requested from the sponsor on June 21, 2012. The spreadsheet was received by e-mail on July 6, 2012, and samples were expected 1-2 weeks later.

#### **3.2.5 Contact GSK to request an update on the status of their responses to the Information Request of April 30, 2012.**

Responses to comments 24 and 26-29 in the Information Request of April 30, 2012, were received on June 20, 2012, in amendment 125419.3. The remaining responses to the IR request are expected on July 18, 2012, per the applicant's email of June 22, 2012.

### **3.3 TEAM REPORTS**

- 3.3.1 Chair/RPM/Regulatory:** The review team was asked to notify the Committee Chair and RPMs about the status of their 1<sup>st</sup> draft reviews. OVRM management stressed the importance of meeting the review timelines, especially with PDUFA 5 being implemented next year.

The review team was instructed to present the status of their reviews and their best advice for approval/non-approval to management at the Mid-Cycle Meeting.

**3.3.2 Clinical**

Clinical reported the review was progressing and that there were no CR issues identified to date. First draft review was completed.

**3.3.3 Statistical**

The Stats reviewers reported that their reviews were progressing. First draft reviews were complete. The Stats reviewer discussed the difficulties in reviewing the Van Buynder study due to the small size of the study and the missing data for the excluded subjects. It was unclear how the results of the Van Buynder study would be represented in a Package Insert. The Stats reviewers were going to present a full, preliminary review of the Van Buynder study, including questions for management, at the Mid-Cycle Meeting.

**3.3.4 CMC/Product:** No Report

**3.3.5 Toxicology:** No Report

**3.3.6 Facilities/DMPQ:** No Report

**3.3.7 Epidemiology (Effectiveness Study):** No Report

**3.3.8 BIMO**

BIMO requested 4 clinical investigator inspections covering Protocol 110464 (FLU Q-PAN-002 PRI) on 4/19/2012, with a requested inspection completion date of 7/10/2012. Two of the four requested inspections were completed (no FDA Form 483 issued to either of the already-inspected parties).

**3.3.9 Pharmacovigilance:** No Report

**3.3.10 Product Testing and Lot Release:** No Report

**3.3.11 Labeling/APLB:**

APLB reported that they would be completing their review after obtaining a draft of the clinical review.

**3.4 MIDCYCLE MEETING**

The Mid-Cycle meeting will be held on July 20, 2012.

#### 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	
6/21/2012	Carmen Collazo-Custodio	Adjuvant lots and SRID calculation spreadsheet	Karen Campbell	-	-	

#### 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.
June 20, 2012 (125419.3)	Partial response to 4/30/2012b IR. Answers to Items 24 and 26-29.