

Meeting Summary, January 7, 2013 - Q-Pan

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

MEETING SUMMARY

Date and Time: January 7, 2013 12:30 am – 1:30 pm

Location: WOC2 – Room 2330

STN #: 125419/0

Sponsor: ID Biomedical Corporation of Quebec (dba GlaxoSmithKline Biologicals)

Product: Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

CBER/FDA Invitees

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

Attended Committee Member	Review Assignment	Supervisor
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

Attended Committee Member

Review Assignment

Supervisor

David Schwab

Electronic Integrity Review

Laraine Henchal

OTHER ATTENDEES:

Wellington Sun
Richard Forshee
Elizabeth Sutkowski
Lewis Schragger
Erik Henchal

1.0

PURPOSE

The objectives of this meeting were:

- A. To update Management on the review progress
- B. To update the review team on the new review timelines
- C. To discuss remaining topics that need 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

Milestone

Projected Date

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 (Delayed by Major Amend.)
Present to PeRC	September 26, 2012
Labeling Comments to Sponsor	November 9, 2012 (FDA Tracked Milestone)
First Action Due	December 22, 2012
Final Reviews (Signed/Uploaded)	February 4, 2013 (Updated due date)
Notify GSK of PMC/PMR	February 15, 2013

Milestone	Projected Date
Labeling Complete	March 5, 2013
Major Amendment Action Due Date	March 23, 2013

Meetings	Date
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
	January 7, 2013
	February 11, 2013
March 11, 2013	
Mid-Cycle Review Meeting	July 20, 2012
PeRC	September 26, 2012
VRBPAC	November 14
SWG	Not Scheduled
Labeling Meetings	October 22, 2012,
	October 25, 2012,
	November 2, 2012,
	December 14, 2012,
	December 20, 2012, January 7, 2013

3.2

Team Reports:

3.1

Chair

Management and reviewers were updated on the new due dates (above) and the status of carton/container and package insert (PI) labeling. A second set of comments regarding the carton/container labels were sent to GSK on 12/21/2012. A second set of

comments regarding the PI label were are? circulating internally and would be ready to send to GSK by 1/11/2013. Reviewers were asked to report any PMCs they anticipated including in the Approval Letter.

3.2

Clinical

Clinical indicated that the final review would be completed by 1/21/2013. Both the Clinical Branch Chief and the DVRPA Division Director indicated that they would have memos in support of the Clinical review uploaded to the EDR by February 4, 2013. Clinical did not have any PMCs to report.

3.3

Statistical

The Statistics reviewers indicated that their reviews are progressing and would be completed by 1/21/2013. The Statistics reviewers did not have any PMCs to report.

3.4

CMC/Product

One CMC review is complete and uploaded to the EDR. The remaining CMC review was waiting for GSK to respond to the 12/20/2012 IR. The CMC reviewers did not have any PMCs to report.

3.5

Facilities/DMPQ

The Facilities reviewer indicated that the final review was waiting for GSK to respond to the 12/20/2013 IR. Facilities may request a PMC regarding GSK's use of -----(b)(4)----- as alternative (b)(4) for storage of the H5N1 Antigen depending on their response to the 12/20/2012 IR.

3.6

Pharmacovigilance

The Pharmacovigilance review was with the supervisor. Pharmacovigilance did not have any PMCs to report.

3.7

DBSQC and Lot Release

Three of the 4 DBSQC reviews were completed. The lot testing plan was completed. DBSQC was waiting on GSK's response to the 1/2/2013 IR regarding the LRP to finalize the last review.

3.8

Toxicology

3.8.1

Review Uploaded to EDR

3.9

Epidemiology (Effectiveness Study)

3.9.4

Review Uploaded to EDR

3.10

BIMO

3.10.1

Review Uploaded to EDR

3.11

APLB

3.11

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	
6/15/2012	Carmen Collazo-Custodio	Questions about location of information in the submission.	-	-	No	
6/21/2012	Carmen Collazo-Custodio	Adjuvant lots and SRID calculation spreadsheet	Karen Campbell	-	No	
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 responses to questions 16, 17d, 18, 21, 22 from the 4/30/2012 IR	Lokesh Bhattacharyya	125419.11	Yes	
8/16/2012	Carmen	IR Regarding GSK's	Manju Joshi,	125419.7	Yes	

Request Date	CBER Rep(s)	Request	CBER Requester for Info	BLA Amendment Response	Review Pending?	Reviewed by and Date Reviewed
	Collazo-Custodio	SRID Results	Rajesh Gupta, Karen Campbell	125419.10		
9/10/2012	Jeremy Wally	Response on Timing of Amendment Submission	-	-	No	
9/25/2012	Jeremy Wally	IR regarding SRID assay and additional comments on VRBPAC and Proper Name	Manju Joshi Carmen Collazo-Custodio	125419.10	Yes	
9/26/2012	Jeremy Wally	September 25, 2012, IR/Comments Follow-Up	-	-	No	
9/28/2012	Carmen Collazo-Custodio	Comments regarding the Pharmacovigilance Plan for Influenza A (H5N1) Virus Monovalent Vaccine (Version 2: July 2012*) provided in the submission of July 18, 2012.	Yandong Qiang	125419.17	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	125419.17	Yes	
10/15/2012	Kirk Prutzman	IR Regarding Clinical Items	Andrea James	125419.15	Yes	
10/16/2012	Carmen Collazo-Custodio	IR Regarding Lot Release Protocol	Karen Campbell	125419.13	Yes	
10/17/2012	Carmen Collazo-Custodio	IR comments: clinical (subgroup analyses) and clarification on filling of AS03 (----- (b)(4)-----)	Andrea James Tsai-Lien Lin Randa Melhem	125419.16 125419.18	Yes	
10/18/2012	Kirk Prutzman	IR Regarding Anti-Microbial Effectiveness Testing	James Kenney	125419.14	Yes	
10/22/2012	Carmen Collazo-	IR comment on GSK's PVP	Yangdong Qiang	125419.17	Yes	

Request Date	CBER Rep(s)	Request	CBER Requester for Info	BLA Amendment Response	Review Pending?	Reviewed by and Date Reviewed
10/31/2012	Custodio Carmen Collazo-Custodio	Request for CRFs for subjects in study Q-Pan-002	Andrea James	125419.15	Yes	
11/5/2012	Kirk Prutzman	IR regarding ---(b)(4)--- ---- levels in the Adjuvant	Hana Golding	125419.19	Yes	
11/8/2012	Carmen Collazo-Custodio	IR regarding further clarification on filling of AS03 (----- (b)(4)----- -----)	Randa Melham	125419.18	?	
11/9/2012	Kirk Prutzman	<i>PI, Carton, Container comments to GSK</i>		125419.20 125419.21		
11/9/2012	Kirk Prutzman	IR regarding HA minimum release acceptance criterion	Tsai-Lien Lin Hana Golding Surender Khurana Manju Joshi	125419.20	Yes	
11/16/2012	Carmen Collazo-Custodio	<i>Additional comments on the Package Insert and the Carton Labels</i>		125419.21		
11/19/2012	Kirk Prutzman	IR Regarding Lot Release Protocol in Amendment 13	Catherine Poole	125419.19	Yes	
11/20/2012	Kirk Prutzman	Additional IR item regarding Lot Release Protocol	Catherine Poole	125419.19	Yes	
11/20/2012	Kirk Prutzman	IR regarding Amendment 16 submitted on November 15, 2012	Andrea James	125419.19	Yes	
11/26/2012	Carmen Collazo-Custodio	IR Regarding the Ste. Foy and the Rixensart/Wavre facilities	Randa Melhem	125419.22	Yes	
11/29/2012	Carmen Collazo-Custodio	Characterization of new working seed banks	Surendur Khurana	125419.19	Yes	
11/30/2012	Carmen Collazo-Custodio	IR regarding cleaning validation	Randa Melhem	125419.22	Yes	
12/1/2012	Carmen Collazo-Custodio	Conference Call Summary and CBER's Response to GSK's Potency Specifications	---	---	No	

Request Date	CBER Rep(s)	Request	CBER Requester for Info	BLA Amendment Response	Review Pending?	Reviewed by and Date Reviewed
12/3/2012	Carmen Collazo-Custodio	Proposal Request to clarify if ---- ----- (b)(4)----- -----.	Randa Melhem	125419.22	Yes	
12/5/2012	Carmen Collazo-Custodio	CBER's comments to GSK's response submitted on November 30, 2012, regarding the proposed Lot Release Protocol.	Karen Campbell			
12/20/2012	Carmen Collazo-Custodio	IR on alternative --- (b)(4)----- used to storage the H5N1----- ----- (b)(4)----	Randa Melhem		Yes	
12/21/2012	Carmen Collazo-Custodio	<i>Second Round or Carton/Container comments</i>	---			
1/2/2013	Kirk Prutzman	IR Regarding LRP	Karen Campbell		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.

Date/STN	Summary
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.
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
November 5, 2012 (125419.14)	Response to IR from CBER dated October 18, 2012 regarding the Anti-Microbial Effectiveness Testing
November 6, 2012 (125419.15)	Response to 2 IRs from CBER dated October 15, 2012, and October 31, 2012, regarding clinical issues
November 15, 2012 (125419.16)	Response to IR from CBER dated October 17, 2012, regarding subgroup analyses of all primary immunogenicity and safety endpoints by age, race and gender in studies Qpan-001, Q-Pan-002 and the ISS analyses.
November 19, 2012 (125419.17)	Responses to 3 Information Requests from CBER dated 9/28/2012, 10/10/2012, and 10/22/2012 regarding the PVP.
November 30, 2012 (125419.18)	Responses to 2 Information Requests from CBER dated 10/17/2012, and 11/8/2012.
November 30, 2012 (125419.19)	Responses to 5 Information Requests from CBER dated 11/5/2012, and 11/19/2012, 2 Irs on 11/20/2012, and 11/29/2012.
December 4, 2012 (125419.20)	Response to PI labeling comments from CBER on November 9, 2012. Response to MRAC IR from CBER dated November 9, 2012.
December 8, 2012 (125419.21)	Response to Carton and Container comments from CBER on November 9, 2012 and November 16, 2012. Response to comments regarding the toxicity study described in Section 8.1, Pregnancy, of the proposed Package Insert from CBER date November 30, 2012.
December 13, 2012 (125419.22)	Response to information requests from CBER dated 11/26/2012, 11/30/2012, and 12/3/2012. Response to questions from telephone-tcons dated 11/29/2012, 11/30/2012, and 12/5/2012.

