

Record of Telephone Conversation, October 24, 2012 - Q-Pan

- Submission Type: BLA
Submission ID: 125419/0
Office: OVRR

Product:

Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

Applicant:

ID Biomedical Corporation of Quebec

Telecon Date/Time: 24-Oct-2012 02:31 PM Initiated by FDA? Yes

Telephone Number: 301-787-3435

Communication Category(ies):

1. Other - CBER's response to GSK

Author: CARMEN COLLAZO-CUSTODIO

Telecon Summary:

CBER's response to GSK's proposal regarding subgroup analyses.

FDA Participants: Carmen Collazo, Jeremy Wally, Kirk Prutzman

Non-FDA Participants: Michael Schwartz, Jillian Horvath, Dominique Barbeau

Telecon Body:

The following was communicated to GSK via e-mail correspondence.

From: Collazo, Carmen

Sent: Wednesday, October 24, 2012 2:31 PM

To: Michael Schwartz

Cc: Wally, Jeremy; Prutzman, Kirk C; Jillian Horvath; Dominique Barbeau; Collazo, Carmen

Subject: RE: IR request STN 125419

Dear Mike,

We have the following response:

1. We agree with your proposed subgroup analyses as listed in the table provided in your October 23, 2012, e-mail correspondence (see below).
2. If results of the analyses conducted in studies Q-Pan-001 and Q-Pan-002 become available sooner than the ISS analyses, please submit those results first.

Regards,

Carmen

From: Michael Schwartz [mailto:michael.p.schwartz@gsk.com]
Sent: Tuesday, October 23, 2012 1:48 PM
To: Collazo, Carmen
Cc: Wally, Jeremy; Prutzman, Kirk C; Jillian Horvath; Dominique Barbeau
Subject: RE: IR request STN 125419

Dear Carmen,

We have discussed your question regarding subgroup analyses and plan to conduct the analyses listed in the table below. We plan to initiate the analyses below immediately and target submission to CBER by November 16. Since these analyses are quite labor intensive, we would like to confirm that these are in-line with the reviewer's request.

We are proposing to conduct the following subgroup analyses:

Study	Age	Race	Gender	Analyses	
Q-001	18-40	18-40	white/nonwhite	M/F	n="2" immunogenicity, reactogenicity, unsolicited AEs
	41-64	41-64			
Q-002	18-40	18-40	white/nonwhite	M/F	immunogenicity*, reactogenicity, unsolicited AEs
	41-64	41-64			
	>64	>64 >75			
ISS #	18-40		white/nonwhite	M/F	MAEs, SAEs, pIMDs and AESIs
	41-64				
	>64				

* except the lot-to-lot consistency
population of controlled trials for H5N1 and H5N1+H1N1

Can you please confirm that CBER agrees with the proposed analyses in response to the IR.

Best Regards,
Mike

From: Collazo, Carmen [mailto:Carmen.Collazo@fda.hhs.gov]
Sent: Wednesday, October 17, 2012 9:34 AM
To: Robert Brobst; Michael Schwartz
Cc: Wally, Jeremy; Prutzman, Kirk C; Collazo, Carmen

Subject: IR request STN 125419

Importance: High

Dear Drs. Schwartz and Brobst,

We have the following requests for additional information regarding STN 125419 (Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted):

1. Please submit results of subgroup analyses of all primary immunogenicity and safety endpoints by age, race and gender in studies Q-Pan-001, Q-Pan-002 and the ISS analyses.
2. In your response provide in the submission of September 10, 2012, (response to question 2), regarding the filling of AS03, you confirmed that b(4) filling methods, -b(4)-----are claimed. Please clarify what you mean by “claimed” and state the method you plan to use for commercial filling. Please clearly state whether you are seeking approval of b(4) methods. If this is the case, please provide the following information:
 - a. Provide a justification for using b(4) filling methods, --b(4)-----

 - b. Explain the circumstances in which you will use –b(4)----- and describe how you will track the adjuvant filled –b(4)-----

Please submit your responses in an amendment to the BLA submission.

If you have any questions about this communication, please contact Kirk Prutzman, Carmen M. Collazo, or Jeremy Wally.

Regards,

Carmen M. Collazo-Custodio, Ph.D.
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Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

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