

Record of Telephone Conversation, August 15, 2012 - Q-Pan

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

Product:
Influenza A (H5N1) Virus Monovalent Vaccine
Applicant:
ID Biomedical Corporation of Quebec
Telecon Date/Time: 15-Aug-2012 05:22 PM Initiated by FDA? Yes
Telephone Number:
Communication Category(ies):
1. Information Request
Author: KIRK PRUTZMAN
Telecon Summary:
Follow questions to GSK's responses to questions 16, 17d, 18, 21, 22 from the 4/30/2012 IR
FDA Participants: KIRK PRUTZMAN, CARMEN COLLAZO, JEREMY WALLY
Non-FDA Participants: MICHAEL SCHWARTZ, ROBERT BROBST
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:

From: Prutzman, Kirk C
Sent: Wednesday, August 15, 2012 5:22 PM
To: Michael Schwartz; robert.d.brobst@gsk.com
Cc: Collazo, Carmen; Wally, Jeremy
Subject: STN 125419 Information Request

Dear Drs. Schwartz and Brobst,

We have the following additional questions and comments after reviewing your response received by CBER on July 18, 2012 to the Information Request (IR) that was sent to you on April 30, 2012.

1. In your response to questions 16 and 18, you indicated that samples were prepared by ---(b)(4)----- at different concentrations to “baseline” drug substance protein and “monovalent formulated drug product matrix”. This was not clear in the original submission because you used wording, such as “The theoretical concentrations of the samples were 60.955, 128.68, 203.69, 353.16 and 503.05 µg/mL ---(b)(4)---. With this new information we reviewed your validation reports of *Protein Content by -----(b)(4)-----* and drug product again and found that you studied

linearity, accuracy and precision of (b)(4) assays for (b)(4) and not for the protein. We do not agree that (b)(4) constitutes a representative protein sample for this assay. Please validate the procedure using representative samples of the -----(b)(4)----- formulated drug product and submit the results.

2. In response to question 17d, you provided results of analysis of two diluted internal controls performed on 3 days by two analysts using two different columns (Table 5).
 1. Two of the dates are "08/01/13" (August 1, 2013 or January 8, 2013) and "12/06/13" (December 6, 2013 or June 12, 2013). These dates cannot be correct. Please provide the correct dates.
 2. Please provide composition of diluted internal control and explain how closely it resembles the drug substance.
 3. The third date in Table 5 is 10/07/02. Has the assay procedure changed since then? Please provide all versions of the SOP since that date identifying the changes.
3. Your response to question 21g has two parts. In the first part you clarified that the concentration used in validation appeared to be incorrect because you included an old and archived version of the SOP in the original submission and you submitted the current version of the SOP. This is acceptable. However, you have not provided data from the Repeatability study performed using concentrations over the Range of the assay ---(b)(4)----- for both squalene and tocopherol, as requested. Please provide the requested data.
4. With reference to your response to question 22, please provide results of your verification of accuracy in the range between ---(b)(4)----- for the -----(b)(4)-----.
5. Regarding the new validation protocol (9000000414PVM004-03) for the polysorbate content in AS03 assay you submitted as Amendment 4, we recommend that you perform repeatability studies at 3 levels of concentrations at the minimum to cover the whole Range of the assay.

Regards,

Kirk Prutzman, PhD

Food and Drug Administration

Primary Reviewer/Regulatory Project Manager

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