

Record of Telephone Conversation, August 10, 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: 10-Aug-2012 10:30 AM Initiated by FDA? Yes
Telephone Number: 888-643-3083
Communication Category(ies):

1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary:

AS03 manufacturing quality discussion

FDA Participants: KIRK PRUTZMAN, JEREMY WALLY, RANDA MELHEM

Non-FDA Participants: LINDA KRAMER, TERRY WARD, ANGELA HAAG, CHRISTINA FREY, GABRIELLE TOURIGNY, LIONEL ELISSALDE, JEAN-CHRISTOPHE BROHEE

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

CBER and GSK met to discuss issues with the AS03 manufacturing process and shipping.

- 1. Container Closure Integrity Testing (CCIT) of AS03:** CBER discussed that GSK had not submitted sufficient information regarding the container closure system for the AS03 vials. CBER indicated that GSK's response to the April 30, 2012, Information Request (Question 24) did not address the issue of ---(b)(4)--- into the AS03 vials. GSK acknowledged that ---(b)(4)--- testing with manual visual inspection is not suitable or sensitive enough for detecting ---(b)(4)--- into the vials. They added that they addressed the integrity of the container closure (-(b)(4)---) by testing for degradation of α -tocopherol during stability studies. CBER stated that testing few samples for degradation does not substitute for a proper validated process of container closure integrity (---(b)(4)---). GSK said that they would look into this issue and get back to CBER.
- 2. Filling of AS03 – equipment and process:** CBER discussed several issues regarding the AS03 filling process. CBER indicated that it was unclear if GSK was proposing to use an -(b)(4)- procedure or not in the filling process of AS03 upon

licensure. GSK indicated that they wanted licensure to use (b)(4) procedures. CBER stated that commercial consistency lots and stability data provided in the submission were for lots filled ---(b)(4)---. CBER stated that filling under (b)(4) process will need to be validated and that GSK should submit stability data on AS03 filled vials under (b)(4). GSK stated that they would verify, and would get back to CBER.

In the submission it was reported that -----(b)(4)-----
-----, and that the conformance lots were manufactured in 2006/2007. CBER requested clarification whether AS03 conformance lots were filled before or after withdrawal of -(b)(4)- from US license. GSK stated that they will check and get back to CBER.

Regarding media fills, GSK reported that each run was for more than (b)(4) vials. They also reported that the media fill runs were performed at a speed of (b)(4) of the routine filling (----(b)(4)----). CBER requested clarification whether the media fills were performed using the ---(b)(4)--- (AS03 container/closure), duration of each media fill and number of vials filled.

CBER told GSK that they need to submit a detailed description of the entire filling process. GSK should at least include information on the equipment used, if the line is used for other products, how many vials are filled/run, and speed for routine and validated filling process, and whether filling of AS03 is performed in (b)(4). GSK stated that they will provide the information in their written response.

3. **Cleaning validation:** CBER asked GSK about the acceptance criteria for conductivity of the ---(b)(4)--- samples, and they stated it is ----(b)(4)----- temperature. CBER asked GSK if they monitor their cleaning process and if they have in-line testing. GSK confirmed that they do. They added that they revalidate their cleaning procedure annually. CBER asked GSK to submit this information in their response.
 1. **Shipping validation:** CBER asked GSK about shipping validation, and GSK stated that they performed simulated validation for winter and summer conditions. They added that they include a ---(b)(4)--- in each shipment. CBER requested that GSK submit the shipping validation.
 2. IDB/GSK has provided a large number of reports in the submission, many of which have been previously submitted, reviewed and approved. CBER requested that GSK/IDB provide a list of all the reports provided, indicating which are new and specific for AS03, and which have been already reviewed and approved.

GSK indicated that they would submit responses to CBER's requests by August 31, 2012.

Call ended.