DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration

1401 Rockville Pike
Rockville, MD 20852-1448

CBER- GSK CONFERENCE CALL SUMMARY

Date and Time:	March 8, 2013, 8:00 AM – 9:00 AM
Location:	CBER Conf. WOC2-2330; Conference call
STN #:	125419/0
Sponsor:	ID Biomedical Corporation of Quebec (dba GlaxoSmithKline Biologicals)
Product:	Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

CBER/FDA ATTENDEES

Carmen Collazo-Custodio
Andrea James
Tsai-Lien Lin
Kirk Prutzman
Lewis Schrager
Elizabeth Sutkowski
Jeremy Wally

GSK ATTENDEES

Donna Boyce
Dominique Descamp
Bruce Innis
Ping Li
Eddie Reilly
Anne Schuind
Mike Schwartz

1.0 PURPOSE

The objective of this conference call was:

- To discuss with GSK an approach for presenting the changes between the D182 datasets and final datasets (referred to as D364 datasets), so that they are submitted in a format that would facilitate a thorough review but help identify the differences in an expedited manner.

2.0 BACKGROUND

GSK notified CBER on February 26, 2013, during labeling negotiations on the Prescribing Information, that ID Biomedical Corporation of Quebec inadvertently did not submit the complete study data package for study FLU Q-PAN-002 with the initial BLA submitted on February 22, 2012. The 37 datasets submitted with the original BLA (referred to as D182

datasets) were not the final datasets (referred to as D364 datasets). In total, 42 D364 datasets as well as 71 Case Report Forms (eCRFs) were not submitted. This is a concern because CBER used the D182 datasets to conduct the clinical and statistical reviews. CBER requested an opportunity to discuss with GSK the best way to present the changes between the D182 and D364 datasets, so that they are submitted in a format that would facilitate a thorough review but help identify the differences in an expedited manner.

On March 1, 2013, GSK provided a table (an Excel spreadsheet) describing the differences between the datasets submitted in the BLA (D182) and the final datasets (D364) generated for study FLU Q-PAN-002. In summary, the table contained the following information: name of the dataset; description of the dataset; designation of the datasets generated for the D42 and D182 analyses; designation of the final datasets that were generated (D364); identification of differences between the D182 and D364 datasets, if any; highlights illustrating the differences between the D182 and D364 datasets; and GSK's comments.

On March 1, 2013, based on the evaluation of the table provided by GSK on March 1, 2013, CBER informed the company that we wanted to discuss the datasets below in more detail during the conference call scheduled for March 8, 2013.

    REACCOD
    REACDOC
    TREATMNT
    WAECOD
    WCONVAC
    WELIG
    WGENMD
    WLYMPH
    WMEDIC
    WNOADM
    WNOVIS
    WSOLIC
    WOCEAN
    WSOLPRE
    WUNSOL
    WVITAL

3.0   DISCUSSION TOPICS

3.1   CBER and GSK discussed the following items regarding the D182 and D364 datasets:

- CBER asked GSK about the two additional variables in the D364 TREATMNT dataset. GSK responded that these variables are pooling analysis and treatment name. These variables were never used.

- CBER asked GSK about the WAECOD dataset in which 5 variables in the D182 dataset were not included in D362 dataset. GSK responded that these variables are related to database cleaning, but did not impact the analysis.

- CBER asked about the PID dataset shown in red on the table provided on March 1, 2013. GSK responded that the dataset was identified in red because it was considered a key dataset, but there were no changes in this dataset.

- CBER added another dataset of interest, the WDROP dataset. This dataset was not included in the list provided by CBER to GSK on March 7, 2013.

- For the datasets identified by CBER on March 1, 2013 (see above), as well as the WDROP dataset mentioned today, CBER asked GSK to submit an itemized list of changes between the D182 datasets and the final D364 datasets and the rationale for each of the changes. CBER also asked GSK to provide a side-by-side comparison (dataset merge) of the D182 and D364 datasets (of the same name) and highlight the differences between each of the datasets to facilitate our review. For instance, if there was a variable change (e.g., temperature change in a subject) between the D182 and D364 datasets, highlight the change and explain why the change occurred.

- Regarding the REACCOD dataset, GSK explained that the data structure changed substantially without standard macro update. In this situation, it is going to be difficult to compare the D182 and D364 datasets. GSK would inform CBER when challenges such as these arise regarding dataset comparisons.

- It was agreed that GSK will provide a sample dataset comparison prior to undertaking this effort on all the requested datasets. GSK will use as an example the WUNSOL dataset because it has the greatest number of changes.

3.2   CBER asked GSK to submit to the BLA the final D364 datasets (to be included in the D364 folder) and the 71 case report forms (eCRFs) that were supposed to be submitted with the original BLA. GSK agreed.

3.3   CBER asked GSK to provide source data regarding the adverse event of "lupus" in subject 1666 and the adverse event of "vasculitis" in subject 5677, both of which were recorded in the D182 WUNSOL dataset and subsequently removed from the D364 WUNSOL dataset.

4   ACTION ITEMS

Action item	Owner
Submit to the BLA final D364 datasets and 71 case report forms (eCRFs)	GSK
Submit to the BLA source data regarding the adverse event of "lupus" in subject 1666 and the adverse event of "vasculitis" in subject 5677	GSK
Provide a sample WUNSOL dataset comparison for discussion and concurrence between CBER and GSK	GSK