RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125614/0.0
Review Office	OVRR
Applicant	GlaxoSmithKline Biologicals / Lic. # 1617
Product	Zoster Vaccine Recombinant, Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	21-FEB-2017 10:25 AM
Author	NAIK, RAMACHANDRA
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	CMC IR regarding clarification on table for the clinical assays, and information on the HAI assay validation reports and SOPs, included in section 5.3.1.4.
FDA Participants	Carmen Collazo-Custodio, Ramachandra Naik and Michael Smith
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: IR in the e-mail message pasted below.

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From: Collazo, Carmen
Sent: Tuesday, February 21, 2017 10:25 AM
To: Jody Gould (jody.a.gould@gsk.com)
Cc: Norris Pyle (norris.h.pyle@gsk.com); Naik, Ramachandra; Smith, Michael (CBER)
Subject: STN 125614/0 (Shingrix): Information Request Clinical Assays in Module 5.3.1.4

Dear Dr. Gould,

Reference is made to the clinical assays provided in Module 5.3.1.4: *Reports of Bioanalytical and Analytical Methods for Human Studies* of your BLA submission. We have the following comments:

1. Please provide a table that correlates the clinical assays included in this section with the corresponding clinical study. In the table, please provide the phase of the study, the endpoint measured (primary, secondary, and exploratory), the time period when the clinical samples were tested and which version of each assay was used, and whether testing results from the clinical assays were reported to CBER in a previous IND submission or in the BLA submission.

2. Regarding the information on the Haemagglutination Inhibition Assay (module 5.3.1.4: (b) (4)), please indicate if the validation reports and SOPs for the HAI assay were previously submitted to CBER for review and provide cross-references. When cross-referencing information, please be as detailed and specific as possible and provide submission date, amendment number, section(s), and page number(s). A letter cross-referencing the BLA should also be submitted to the cross-referenced submission with specific information (e.g., BLA submission number, date of submission, purpose of the submission) to be able to establish a link between the cross-referenced submission and the BLA (and future BLA supplements).

Please confirm receipt of this message and provide your responses in an amendment to STN 125614/0 by March 3, 2017. In your reply to this communication, we recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions about this communication, please contact Dr. Carmen M. Collazo-Custodio at (301) 796-2640.

Carmen M. Collazo-Custodio, Ph.D.
Microbiologist (Team Leader)

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration

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