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	16-NOV-2016 01:00 PM
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	Clarification regarding ISS and ISE datasets, and SAE narratives
FDA Participants	Ramachandra Naik Carmen Collazo-Custodio Paula Agger Meghan Ferris Andrea Hulse
Applicant Participants	**Jody Gould**, Head, US Policy & Intelligence and Business Excellence, US Lead Zoster North American Regulatory Affairs, Vaccines **Lidia Oostvogels**, Director, Clinical and Epidemiology Project Leader Herpes Zoster Vaccine, Clinical RDC Belgium **Tamzin Tanner**, Senior Manager, Global Regulatory Affairs **Fernanda Tavares**, Director, Head of Safety Evaluation and Risk Management **Carla Vinals**, Director, Global Regulatory Lead Herpes Zoster vaccine **Elodie Garric**, Expert Scientist, Safety

Telecon Body:
Regarding the Integrated Summary of Safety (ISS): CBER stated that at this time in the review cycle, we are looking at the adequacy of the submission (not the adequacy of the data) and noted that the ISS consists of only tables; it has no text. CBER inquired if that was what GSK meant to submit. CBER reminded GSK that during the Pre-BLA meeting,

CBER specifically asked for a more comprehensive ISS with text, and noted that the ISS could include links to the Summary of Clinical Safety (SCS) to avoid repetition of information included in the ISS text, when appropriate. GSK replied that they intended to submit all related tables (actual data) without text in the ISS, and stated that the related text and discussion of analyses are in the SCS. CBER asked if the text in the SCS references and links to every table in the ISS. GSK confirmed that this was the case. CBER acknowledged GSK's response stating that pending review of the entire SCS and ISS, CBER is relying on GSK's assessment. However, during the review cycle if CBER encounters an issue with the completeness of the SCS, as it pertains to rendering the currently incomplete ISS complete, we may need to contact GSK for further information/analyses.

Regarding the Integrated Summary of Efficacy (ISE): CBER stated that there are no datasets located under the ISE, and asked if datasets which appear to be related to efficacy found under the ISS are actually the ISE datasets, and additionally inquired whether all integrated efficacy datasets have been submitted. GSK responded that the efficacy datasets are under each report for the studies ZOSTER-006 and ZOSTER-022 and that the efficacy datasets for the pooled analyses are under ZOSTER-022. However, GSK will get back to CBER later, to confirm and to clarify regarding the efficacy datasets located under the ISS.

Regarding narratives for serious adverse events (SAEs): CBER asked if GSK included narratives for all SAEs from each study and, if so, asked for the location of the information in the submission. GSK responded that they have submitted all SAE narratives appended to each clinical summary.

Call ended.