

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-DEC-2016 09:00 AM
Author	NAIK, RAMACHANDRA
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Clarification regarding SAPs for studies Zoster-006, Zoster-022, Zoster-026, Zoster-004, Zoster-007
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: CBER asked if GSK has included Statistical Analysis Plans (SAPs) for the studies - Zoster-006, Zoster-022, Zoster-026, Zoster-004 and Zoster-007, in their submission to the BLA (STN 125614/0) dated October 21, 2016. GSK stated that SAPs were not included in the BLA submitted on October 21, 2016, because the Key SAPs for the studies mentioned were submitted to IND 13857 previously for CBER review and comment, and since statistical analyses were carried out according to the SAPs as

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updated per feedback from CBER, the SAPS were not submitted in the BLA. CBER requested GSK to resubmit SAPs (all revisions and the final versions) for the studies mentioned above for ease of review. GSK agreed.

Call ended.