

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	09-DEC-2016 01:17 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	IR regarding Statistical Analysis Plans for studies Zoster-004, -006, -007, -022 and -026
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: IR e-mail message pasted below.

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From: Naik, Ramachandra

Sent: Friday, December 09, 2016 1:17 PM

To: Jody Gould

Cc: Norris Pyle; Smith, Michael (CBER); Collazo, Carmen

Subject: STN 125614/0: SAPs for studies Zoster-004, -006, -007, -022 and -026

Dear Dr. Gould,

In your submission to the BLA (STN 125614/0) dated October 21, 2016, CBER couldn't find the Statistical Analysis Plans (including all amendments) for the studies - Zoster-006, Zoster-022, Zoster-026, Zoster-004 and Zoster-007. Please let us know if SAPs for these studies were included in the submission or not. If included, please let us know the file names and location in the submission.

Regards,
Ram

Ramachandra S. Naik, Ph.D.

Chemist (Regulatory) / Regulatory Project Manager

**Center for Biologics Evaluation and Research
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