

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

Telecon Details

Telecon Date/Time	17-MAR-2017 09:05 AM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Summary of the 3/6/2017 telecon with GSK held to discuss several clinical issues including clarification regarding number of subjects with events occurring from first dose to 30 days post last vaccination period, and IR for other clinical issues
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body:

- Summary of the 3/6/2017 telecon, and IR for other clinical issues were sent in an e-mail.
- E-message pasted below.
- The e-mail attachment containing the summary of the 3/6/2017 telecon and the IR for other clinical issues, is uploaded to EDR as 3/6/2017 telecon summary.

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From: Naik, Ramachandra

Sent: Friday, March 17, 2017 9:05 AM

To: 'Jody Gould'

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

Subject: STN 125614/0 Shingrix BLA: Summary of March 6, 2017, telecon regarding clinical issues

Dear Dr. Gould,

Please find attached the summary of the 3/6/2017 telecon regarding STN 125614/0 (Zoster Vaccine Recombinant, Adjuvanted). Please provide your responses in an Amendment to STN 125614/0.

Please confirm receipt of this message and let us know your estimated timeline for providing the requested information.

Please let us know if you have any questions or need additional information.

Regards,

Ram

Ramachandra S Naik, Ph.D.

Primary Reviewer/Regulatory Project Manager

Food and Drug Administration

CBER/OVRR/DVRPA/RRB3

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