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	02-AUG-2017 02:59 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Clinical IR regarding neuralgia adverse events
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould, Norris Pyle and Linda Kramer

Telecon Body: IR e-mail message pasted below.

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From: Naik, Ramachandra
Sent: Wednesday, August 02, 2017 2:59 PM
To: 'Jody Gould'
Cc: Collazo, Carmen; Smith, Michael (CBER); 'Norris Pyle'; 'Linda Kramer'
Subject: STN 125614/0: Clinical IR regarding neuralgia adverse events

Dear Dr. Gould,

Our review of the information provided in your BLA dated October 21, 2016, for Zoster Vaccine Recombinant, Adjuvanted, is ongoing. We have the following request for additional information:

In Tables 92 and 130 of your CSR for study Zoster-033, six subjects ((b) (6)) were reported to have a total of nine suspected HZ episodes.
In Table 93, two subjects ((b) (6)) were reported to have adverse events of post-herpetic neuralgia that resulted in withdrawal from the study.
Additionally, in Table 82, one adverse event each of neuralgia and facial neuralgia were reported to have causal association with vaccination.
Please provide a full narrative for each of these four adverse events of neuralgia, including baseline medical history and medications, dates of onset of the event of neuralgia, the action taken, and any additional preceding or concomitant adverse events, and whether these subjects were diagnosed with HZ.

Please provide your responses, in an amendment to STN 125614/0, by Wednesday, August 9, 2017.

Please confirm receipt of this message, and let us know if you have any questions or need additional information.
Regards,
Ram

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