

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125614/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	GlaxoSmithKline Biologicals / Lic. # 1617
<b>Product</b>	Zoster Vaccine Recombinant, Adjuvanted

## Telecon Details

<b>Telecon Date/Time</b>	02-AUG-2017 02:59 PM
<b>Author</b>	NAIK, RAMACHANDRA
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Telecon Summary</b>	Clinical IR regarding neuralgia adverse events
<b>FDA Participants</b>	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
<b>Applicant Participants</b>	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

**Ramachandra S Naik, Ph.D.**

Primary Reviewer/Regulatory Project Manager

Food and Drug Administration

CBER/OVRR/DVRPA/RRB3

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