

# 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>	20-JUL-2017 03:51 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 subject 18662 and pIMD
<b>FDA Participants</b>	Carmen Collazo, Michael Smith and Ramachandra Naik
<b>Applicant Participants</b>	Jody Gould and Norris Pyle

**Telecon Body:** IR e-mail message pasted below.

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**From:** Collazo, Carmen  
**Sent:** Thursday, July 20, 2017 3:51 PM  
**To:** Jody Gould (jody.a.gould@gsk.com)  
**Cc:** Smith, Michael (CBER); 'Norris Pyle'; Naik, Ramachandra  
**Subject:** STN 125614/0: IR regarding pIMD and subject 18662  
**Importance:** High

Dear Dr. Gould,

We have the following request for clarification:

We note that in Table 70 of the Zoster-022 Clinical Study Report (page 443), eczema is listed as a pIMD; however, in Section 5.3.5.3 (*Patient Narratives*) the serious adverse event of “exacerbation of eczema” (subject 18662, page 23) is not listed as a pIMD. Please clarify.

Please provide your responses, in an amendment to STN 125614/0, by Friday, July 28, 2017.

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

Regards,

Carmen

**Carmen M. Collazo-Custodio, Ph.D.**

*Microbiologist (Team Leader)*

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