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	20-JUL-2017 03:51 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Clinical IR regarding subject 18662 and pIMD
FDA Participants	Carmen Collazo, Michael Smith and Ramachandra Naik
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: IR e-mail message pasted below.

RECORD OF TELEPHONE CONVERSATION

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)

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
carmen.collazo@fda.hhs.gov