

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	08-SEP-2017 08:43 AM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	CMC IR regarding calculation of gE potency ratio
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Norris Pyle and Jody Gould

Telecon Body: IR e-mail message pasted below.

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From: Naik, Ramachandra
Sent: Friday, September 08, 2017 8:43 AM
To: 'Norris Pyle'
Cc: Collazo, Carmen; Smith, Michael (CBER); 'Jody Gould'
Subject: STN 125614/0: CMC IR regarding calculation of gE potency ratio

Dear Mr. Pyle,

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

Section P.5.6 Justification of Specifications, subsection "Potency gE by (b) (4) (page 1 and 3), defines the gE potency as the (b) (4), obtained by (b) (4) and (b) (4) obtained by (b) (4). Additionally, this section explains that the potency specification is aligned with the specification for (b) (4)

However, according to SOP 9000037069, the gE potency for final container is determined as a (b) (4)

Please clarify these inconsistencies and revise the relevant sections of the BLA as appropriate.

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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