

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 03:18 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	CMC IR regarding process-related impurities for the gE and AS01 drug product final containers
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Norris Pyle, Jody Gould and Linda Kramer

Telecon Body: IR e-mail message pasted below.

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From: Naik, Ramachandra

Sent: Wednesday, August 02, 2017 3:18 PM

To: 'Norris Pyle'

Cc: Collazo, Carmen; Smith, Michael (CBER); Linda Kramer; Jody Gould

Subject: STN 125614/0: CMC IR regarding process-related impurities for the gE and AS01 drug product final containers

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 comment pertaining to process-related impurities for the gE and AS01 drug product (DP) final containers:

In addition to the process-related impurities listed in section P.5.5 for the gE DP and AS01 DP, please provide a list of all materials such as materials used as (b) (4)

. In addition, please provide an assessment about their amounts in each of the final DPs.

Please provide your responses, in an amendment to STN 125614/0.

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
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