

# 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>	03-AUG-2017 04:31 PM
<b>Author</b>	NAIK, RAMACHANDRA
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Telecon Summary</b>	CMC-DBSQC IR regarding validation data on (b) (4) [REDACTED]
<b>FDA Participants</b>	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
<b>Applicant Participants</b>	Norris Pyle, Jody Gould and Linda Kramer

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

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**From:** Naik, Ramachandra

**Sent:** Thursday, August 03, 2017 4:31 PM

**To:** 'Norris Pyle'


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

**Subject:** STN 125614/0: CMC IR regarding validation data on (b) (4)

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 request for additional information:

(b) (4)



Please provide the requested data/information in an amendment to STN 125614/0, by Friday, September 1, 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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