

# 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>	8-JUN-2017 12:28 PM
<b>Author</b>	NAIK, RAMACHANDRA
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Telecon Summary</b>	IR regarding GSK's rationale for using the reconstituted vaccine within 6 hours
<b>FDA Participants</b>	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
<b>Applicant Participants</b>	Jody Gould and Norris Pyle

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

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**From:** Naik, Ramachandra  
**Sent:** Thursday, June 08, 2017 12:28 PM  
**To:** Jody Gould; Norris Pyle  
**Cc:** Collazo, Carmen; Smith, Michael (CBER)  
**Subject:** STN 125614/0: Shingrix in-use stability

Dear Jody and Norris,

We have a comment regarding in-use stability of Shingrix. You state in the Prescribing Information and the Carton-Container labels that after reconstitution, Shingrix can be administered within 6 hours, and it is to be discarded if not used within 6 hours. In addition, protocols for Zoster-006 and Zoster-022 provide instructions to use Shingrix within 2 hours after reconstitution. We acknowledge the in-use stability data provided for the gE/AS01<sub>B</sub> Reconstituted Vaccine in the BLA submission. Please explain your rationale for using the reconstituted vaccine within **6 hours** in your labels.

Please let us know if you have any questions or need additional information.

Regards,

Ram

**Ramachandra S Naik, Ph.D.**  
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