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	8-JUN-2017 12:28 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	IR regarding GSK's rationale for using the reconstituted vaccine within 6 hours
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	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$_B$ 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.
Primary Reviewer/Regulatory Project Manager
Food and Drug Administration
CBER/OVRR/DVRPA/RRB3
10903 New Hampshire Avenue
Building 71, Room 3045
Silver Spring, MD 20993
Phone: (301) 796-2640
FAX: (301) 595-1244