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-JUN-2017 02:27 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Pharm-Tox IR regarding serology report for the reproductive toxicology study HEY0005
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: E-mail message and the IR attachment pasted below.

RECORD OF TELEPHONE CONVERSATION

From: Naik, Ramachandra
Sent: Thursday, June 08, 2017 2:27 PM
To: 'Jody Gould'
Cc: Collazo, Carmen; Smith, Michael (CBER); Norris Pyle
Subject: STN 125614/0: IR regarding serology report for the reproductive toxicology study HEY0005

Dear Dr. Gould,

Attached is a request for additional information regarding STN 125614/0 (Zoster Vaccine Recombinant, Adjuvanted). Please provide your responses, in an amendment to STN 125614/0, by Friday, June 16, 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
10903 New Hampshire Avenue
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CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF VACCINES RESEARCH AND REVIEW
DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS

Date: **June 8, 2017**

Pages: **2**

To: **Jody Gould, Ph.D.**
Senior Director
North American Regulatory Affairs, Vaccines
GlaxoSmithKline Biologicals
14200 Shady Grove Road
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Rockville, MD 20850
Telephone: (610) 917-2985 Fax: (240) 238-9822

From: **Division of Vaccines and Related Products Applications**
Office of Vaccines Research and Review
Point of Contact: Ramachandra Naik, Ph.D.
Regulatory Project Manager
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Silver Spring, MD 2993-0002
Telephone: (301)-796-2640 Fax: (301)-595-1124

STN: **125614/0**

Product: **Shingrix (Zoster Vaccine Recombinant, Adjuvanted)**

Subject: **Request for additional information**

Dear Dr. Gould,

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

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1. In module 4.2.3.5.3 for the Nonclinical Study Report (b) (4) 0005: Zoster Candidate Vaccine (gE/AS01B): Study of Effects on Embryo-Fetal, Pre- and Post natal Development in CD Rats by Intramuscular Administration (Including Pre-Mating Immunisation Phase), you state in section 2.4.7 *Biosampling (antibody assay)* that "The results of these analyses are not included in this report but will be reported as a separate study." We could not find this study report in the submission (STN 125614/0). Please let us know the file names and location in the submission if this serology report was included in the submission. If not, please submit the study report to us for our review.

Please provide your responses, in an Amendment to STN 125614/0, by Friday, June 16, 2017. We recommend that you restate the item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions about this communication, please contact Ramachandra Naik, Ph.D. or Michael Smith, Ph.D. at (301) 796-2640.