

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	06-APR-2017 11:47 AM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Request for additional CMC Information
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Norris Pyle and Jody Gould

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

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From: Naik, Ramachandra

Sent: Thursday, April 06, 2017 11:47 AM

To: 'Norris Pyle'

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

Subject: STN 125614/0 Shingrix BLA: Request for additional CMC Information

Dear Mr. Pyle,

Attached is a request for additional CMC information regarding STN 125614/0 (Zoster Vaccine Recombinant, Adjuvanted). Please provide your responses, in an amendment to STN 125614/0, by Thursday, April 20, 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

Building 71, Room 3045

Silver Spring, MD 20993

Phone: (301) 796-2640

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CENTER FOR BIOLOGICS EVALUATION AND RESEARCH OFFICE OF VACCINES RESEARCH AND REVIEW DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS

Date: April 6, 2017

Pages: 2

To: Norris Pyle
North American Regulatory Affairs, Vaccines
GlaxoSmithKline Biologicals
14200 Shady Grove Road
VR1500
Rockville, MD 20850
Telephone: (610) 917-4086 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
10903 New Hampshire Ave., White Oak Bldg. 71
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 CMC Information

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 CMC Information:

1. Regarding the testing performed for qualification of (b) (4), please define acceptance criteria for the (b) (4) test performed by (b) (4).
2. Regarding the (b) (4), we note your intent of establishing provisional limits for the (b) (4) batches manufactured in 2014 and (b) (4) additional batch planned in 2016 (communicated in IND 13857 Amendment 231). Please provide the provisional limits for the (b) (4).

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3. Please provide the name, source and qualification procedures for the (b) (4) used for each of the (b) (4).
4. Please provide the name, source, specification, qualifications including extractables & leachables information for the (b) (4) that will be used in the (b) (4).
5. Please provide a list of the drug product release tests performed at the (b) (4) facility and validation studies on the transferred assays.
6. Please provide the manufacturing dates and hold time (duration of the long-term storage at (b) (4)) for the gE (b) (4) batches used in the manufacturing of clinical trial and commercial batches.

Please provide your responses, in an Amendment to STN 125614/0, by Thursday, April 20, 2017. We recommend that you restate each 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.