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	27-JUN-2017 03:35 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	CMC IR regarding Container, Closure and Leachables
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Norris Pyle and Jody Gould

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

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From: Naik, Ramachandra
Sent: Tuesday, June 27, 2017 3:35 PM
To: 'Norris Pyle'
Cc: Jody Gould; Collazo, Carmen; Smith, Michael (CBER)
Subject: STN 125614/0: CMC IR regarding Container, Closure and Leachables

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 Wednesday, July 12, 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 27, 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 information:

1. Regarding the (b) (4) caps, please clarify if this container closure system is the same for the QS21 (b) (4) as well as for storage of the gE (b) (4) .

2. Regarding the $AS01_B$ drug product (DP) final container closure system (Type (b) (4) glass vials with (b) (4) rubber stoppers):

    a. The summary of the leachable study was not detailed enough. Please provide information on the lots tested, the storage conditions used and results of data

points covering the proposed shelf life. Please provide a summary of the leachables study(ies) and the study report(s).

b. We note your finding of a leachable from the (b) (4) stopper identified as (b) (4) during QC analysis of QS-21 content. A retrospective investigation of the (b) (4) supports the presence of (b) (4). Please provide information on any follow-up investigations you have performed regarding (b) (4) in all your licensed vaccines that utilize these stoppers.

3. Regarding the gE and $AS01_B$ final container closure system (3 mL type (b) (4) glass vials), please provide the name of the supplier(s) of the 3 mL glass vials and confirm that the gE and $AS01_B$ DP vials are the same. Please provide a list of GSK's US-licensed vaccines filled in the same vials.

4. Regarding the gE DP container closure system (3 mL type (b) (4) glass vials with (b) (4) rubber stoppers):

   a. Please clarify if the leachable study was performed only on (b) (4) of gE DP ((b) (4)) and provide available data for time points beyond the 12-month time period. If the study was completed, please provide the study report. If additional studies were conducted with developmental lots, please provide a summary of these studies.

   b. Please provide a list of GSK's US-licensed vaccines that use the same (b) (4) rubber stoppers.

Please provide your responses, in an Amendment to STN 125614/0, by Wednesday, July 12, 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.