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	24-JUL-2017 01:07 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	CMC IR regarding manufacturing quality
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo
Applicant Participants	Norris Pyle and Jody Goud

Telecon Body: IR e-mail message pasted below.

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From: Naik, Ramachandra
Sent: Monday, July 24, 2017 1:07 PM
To: 'Norris Pyle'
Cc: Collazo, Carmen; Smith, Michael (CBER); 'Jody Gould'
Subject: STN 125614/0: CMC IR regarding manufacturing quality

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 comment and request for additional information:

1. Regarding the microbial retention studies performed for the (b) (4) of the $AS01_B$ Adjuvant (b) (4) (document VA-0000060619) and MPL (b) (4) (document 20121265_FR_(b) (4) _Annex 1_(b) (4) please provide data that support the viability of the test organism used in these studies ((b) (4)) in the test articles at the (b) (4) .

2. Regarding the microbial retention study performed for the (b) (4) of the MPL (b) (4) (document 20121265_FR (b) (4) _Annex 1_(b) (4)), please clarify the (b) (4) that were used for the (b) (4) during this study as well as the (b) (4) that is used for the (b) (4) used during routine manufacturing.

3. Regarding the cleaning validation for the manual cleaning of the (b) (4) (document WN20110741) provided in the amendment of June 30, 2017, we have the following comments:

    a. The study reports state that a (b) (4) was established based upon this validation. However, the actual (b) (4) used during the runs to support the proposed (b) (4) were not supplied in the report. Please provide the actual (b) (4) for these runs.

    b. Swab samples do not appear to have been collected during the validation. Please provide a rationale for why such samples are not needed and how you assess the cleanliness of the hardest to reach locations that may not be able to be seen during visual inspection (if any exist).

    c. Please clarify if these validation runs were performed by different operators.

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If you have any questions about this communication, please contact Ramachandra Naik, Ph.D. or Michael Smith, Ph.D. at (301) 796-2640.
Regards,
Ram

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