

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
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	22-NOV-2016 02:22 PM
Author	NAIK, RAMACHANDRA
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	IR regarding Endotoxin test validation reports (recalculation)
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Norris Pyle and Jody Gould

Telecon Body: IR e-message pasted below.

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From: Naik, Ramachandra
Sent: Tuesday, November 22, 2016 2:22 PM
To: Norris Pyle
Cc: Jody Gould; Collazo, Carmen; Smith, Michael (CBER)
Subject: STN 125614/0 IR regarding Endotoxin test

Dear Dr. Norris,

Thank you for the information. This is to confirm that those were the information that we needed. However, we have the following request for additional information:

Please recalculate the (b) (4) for the endotoxin test in (b) (4) drug product report (no. 9000002991 RVM 001.12) using the updated release specifications of (b) (4) respectively. Please submit these reports as an amendment to your BLA STN 125614/0.

Please confirm receipt of this message and let us know your estimated timeline for providing the requested information. Please let us know if you have any questions or need additional information.

Regards,
Ram

From: Norris Pyle [<mailto:norris.h.pyle@gsk.com>]
Sent: Friday, November 18, 2016 1:31 PM
To: Naik, Ramachandra
Cc: Jody Gould
Subject: Subject: STN 125614/0 IR regarding Endotoxin and Sterility test qualification reports

Hi Ram,

For the below request that you sent to Jody yesterday, the following reports are in 3.2.R of the BLA:

- Validation Sterility Tests by (b) (4)
- Validation Sterility Tests by (b) (4) (this is final container)
- Validation Endotoxin Content by (b) (4)
- Validation Endotoxin Content by (b) (4) (this is final container)
- Validation Sterility Tests by (b) (4)

Let me know if these are what you need, or if you are looking for additional information. Thank you - Norris

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We have the following requests for additional information:

1. Please provide complete endotoxin test qualification reports for (b) (4) drug product.
2. Please provide complete sterility test qualification reports for HZ/su drug product and adjuvant AS01_B.

Please confirm receipt of this message and let us know your estimated timeline for providing the requested information. Please let us know if you have any questions or need additional information.

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