

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	03-AUG-2017 02:13 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	CMC IR regarding Certificate of Analysis for a (b) (4) used for manufacture of QS-21 (b) (4)
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Norris Pyle, Jody Gould and Linda Kramer

Telecon Body: IR e-mail message pasted below.

RECORD OF TELEPHONE CONVERSATION

From: Naik, Ramachandra

Sent: Thursday, August 03, 2017 2:13 PM

To: 'Norris Pyle'

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

Subject: STN 125614/0: CMC IR regarding Certificate of Analysis for a (b) (4) used for manufacture of QS-21 (b) (4)

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. Please submit a Certificate of Analysis for a (b) (4) used for manufacture of QS-21 (b) (4).

Please provide your responses, in an amendment to STN 125614/0.

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

FAX: (301) 595-1244

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.