

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	05-JUL-2017 09:49 AM
Author	SMITH, MICHAEL
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Three IR's from DBSQC regarding validation reports
FDA Participants	Mike Smith, Ram Naik and Carmen Collazo
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body:

See e-mail below.

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From: Smith, Michael (CBER)

Sent: Wednesday, July 05, 2017 9:49 AM

To: 'Jody Gould'; 'Norris Pyle'


Cc: Collazo, Carmen; Naik, Ramachandra

Subject: STN 125614/0: Three IR's from DBSQC regarding validation reports


Jody and Norris,

The Division of Biological Standards and Quality Control (DBSQC) has three information requests (IR's) regarding validation reports.


(b) (4)



(b) (4)



(b) (4)



Please provide the requested data/information within 4 weeks from the date of receipt of this request.

Regards,

Mike

- Please confirm receipt of this IR.

Mike Smith, Ph.D.

Captain, United States Public Health Service

Senior Regulatory Reviewer

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United States Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
Division of Vaccines and Related Products Applications

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