

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125614/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	GlaxoSmithKline Biologicals / Lic. # 1617
<b>Product</b>	Zoster Vaccine Recombinant, Adjuvanted
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	06-JUL-2017 05:19 PM
<b>Author</b>	SMITH, MICHAEL
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	No
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Follow-up guidance regarding safety results for IND and non-IND clinical studies containing the ASO1B adjuvant system
<b>FDA Participants</b>	Mike Smith, Ram Naik and Carmen Collazo
<b>Applicant Participants</b>	Jody Gould and Norris Pyle

### Telecon Body:

See two e-mails below.

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**From:** Smith, Michael (CBER)

**Sent:** Thursday, July 06, 2017 5:19 PM

**To:** 'Jody Gould'

**Cc:** Collazo, Carmen; Naik, Ramachandra; 'Norris Pyle'

**Subject:** RE: STN 125614/0: IR regarding safety results for IND and non-IND clinical studies containing the ASO1B adjuvant system

Jody,

After further consideration, the review team would like information from completed studies for other formulations of AS01, such as AS01E, provided in the proposed tabular format. Please submit this information with the proposed information on AS01B.

Regards,

Mike

- Please confirm receipt of this e-mail.

**From:** Smith, Michael (CBER)

**Sent:** Wednesday, July 05, 2017 1:53 PM

**To:** 'Jody Gould'

**Cc:** Collazo, Carmen; Naik, Ramachandra; Norris Pyle

**Subject:** RE: STN 125614/0: IR regarding safety results for IND and non-IND clinical studies containing the ASO1B adjuvant system

Jody,

Your proposal describes what the clinical team is looking for and the July 21<sup>st</sup> date is acceptable. However, please send us the information before then if it is ready sooner (even if it is an identical version via e-mail).

Regards,

Mike