

# 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

## Telecon Details

<b>Telecon Date/Time</b>	18-APR-2017 09:53 AM
<b>Author</b>	NAIK, RAMACHANDRA
<b>FDA Originated?</b>	No
<b>Communication Categories</b>	IR - Information Request
<b>Telecon Summary</b>	Clarification from GSK regarding amendment 16: Error in number of events reported (in response to Q9, amendment 16, submitted on 4/14/2017) because the analysis was erroneously done taking into account D0-D365 instead of D0-D364.
<b>FDA Participants</b>	Ramachandra Naik, Carmen Collazo-Custodio and Michael Smith
<b>Applicant Participants</b>	Norris Pyle and Jody Gould

**Telecon Body:** GSK sent an e-mail message informing CBER that GSK has identified an error in their submission in amendment 16 dated April 14, 2017. GSK's e-mail message pasted below.

## RECORD OF TELEPHONE CONVERSATION

**From:** Norris Pyle [mailto:norris.h.pyle@gsk.com]  
**Sent:** Tuesday, April 18, 2017 9:53 AM  
**To:** Naik, Ramachandra; Collazo, Carmen  
**Cc:** Smith, Michael (CBER); Jody Gould  
**Subject:** RE: Zoster BLA Response Delivery Confirmation

Hi Ram and Carmen,

For the submission below, GSK has identified an error:

- In the ISS analyses submitted in the BLA when we look at events reported up to Day 365, the analysis is done taking into account D0-**D364**.
- In the response to Q9, the analysis was erroneously done taking into account D0-**D365**.
  - ➔ The result is that now there are more events reported in the response than in the BLA due to this additional day. This will need to be corrected for accuracy and aligned between analyses.

We apologize for this. GSK already has the correction ready and is working to submit it as soon as possible (in two or three days). I will give you an exact date shortly. - Norris

**From:** Norris Pyle  
**Sent:** Friday, April 14, 2017 8:12 AM  
**To:** 'Naik, Ramachandra'; Collazo, Carmen  
**Cc:** Smith, Michael (CBER); Jody Gould  
**Subject:** FW: Zoster BLA Response Delivery Confirmation

Hi Ram and Carmen,

GSK's responses were submitted today for CBER's clinical information request sent on March 17 – the gateway information is attached. - Norris

**From:** Jeff Melchiore  
**Sent:** Friday, April 14, 2017 8:04 AM  
**To:** Norris Pyle  
**Cc:** Arlene Grzeszczak  
**Subject:** Zoster BLA Response Delivery Confirmation

Hi Norris,

The above referenced submission has been sent today, **14Apr2017 at 7:49 AM**. Attached to this email is the acknowledgement. Thank you for your help.

**Regards,**

**Jeff Melchiore**  
**Principal Submission Spec.**  
Regulatory Operations  
RD Chief Regulatory Office

**GSK**

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1250 South Collegeville Road Collegeville, PA 19426-0989

**Email** [jeff.s.melchiorre@gsk.com](mailto:jeff.s.melchiorre@gsk.com)

**Tel** +1 610 917 2752

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