

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	03-FEB-2017 06:34 AM
Author	COLLAZO-CUSTODIO, CARMEN
EDR	No
Post to Web	No
Outside Phone Number	610-917-4086
FDA Originated?	No
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	CBER advised GSK (via e-mail correspondence) to submit the remaining 24-month stability data for the PPQ gE drug product lots as an amendment to the BLA by June 2017.
FDA Participants	Carmen Collazo-Custodio, Ramachandra Naik and Michael Smith
Applicant Participants	Norris Pyle and Jody Gould

Telecon Body: E-mail communication shown below.

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From: Collazo, Carmen
Sent: Friday, February 03, 2017 6:34 AM
To: 'Norris Pyle'; Naik, Ramachandra; Smith, Michael (CBER)
Cc: Jody Gould
Subject: RE: Zoster: BLA Amendments

Dear Norris,

Good morning! Please submit the remaining 24-month stability data for the PPQ gE drug product lots by June 2017. Please confirm that you received this message. Thank you!!

Regards,

Carmen

From: Norris Pyle [mailto:norris.h.pyle@gsk.com]
Sent: Thursday, February 02, 2017 10:19 AM
To: Collazo, Carmen; Naik, Ramachandra; Smith, Michael (CBER)
Cc: Jody Gould
Subject: Zoster: BLA Amendments

Hi everyone,

As you know, GSK is working on the BLA amendment for March that includes stability data. As part of the stability data to be provided in March, for PPQ gE drug product lots (outlined in the attached Annex 2 from pre-BLA briefing document; Table 3, page 4) the March stability data was to include only (b) (4) and *in-vitro* potency by (b) (4) data, and the remaining 24m data for these lots would be available by June 2017. I just want to confirm whether or not GSK can submit the remaining 24 month stability data in June for the PPQ lots. Seems this was never directly addressed.

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