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	13-JUN-2017 05:26 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	No
Communication Categories	AD - Advice
Telecon Summary	GSK submitted, in an e-mail, their proposal and timelines for submission of safety information and results of safety analyses, in response to teleconference discussions (of 4/20/2017, 4/28/2017, 5/3/2017 and 5/8/2017) and CBER's 5/10/2017 written advice.
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo
Applicant Participants	Jody Gould

Telecon Body: GSK's e-mail message (page 2) and the .pdf proposal attachment (page 4) pasted below.

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From: Jody Gould [mailto:jody.a.gould@gsk.com]
Sent: Tuesday, May 16, 2017 6:35 PM
To: Naik, Ramachandra
Cc: Collazo, Carmen; Smith, Michael (CBER)
Subject: STN BL125614 - Proposal for the submission of safety information
Importance: High

Dear Ram,

Following recent TC discussions (April 20, April 28, May 3 and May 8) and written advice (May 10) from CBER, GSK has prepared the attached proposal for the submission of safety information and results of safety analyses. The proposal describes 4 submission packages (staggered) and includes 709 additional analyses to be performed.

Note that the proposal outlines output/tables for each submission; GSK will include in each package its discussion and/or summary position related to the data provided.

GSK has also included a number of questions within the document (see boxed questions in bold italic) and respectfully asks for CBER's feedback on these questions to ensure the requested analyses are performed accurately. We hope this format helps facilitate the review and feedback from CBER. Of course, any other input on the proposal is welcome.

Please note that we sent the following request for clarification on May 12 *[Note: this request for clarification is included in the proposal document in Section 3.4.2]*:

> We have one point for clarification:
> In the post-meeting note in the summary of the April 28th TC, there was the following request:
>
> > *For safety evaluations by sex, please include analyses by age and sex using the following age groups 50 – 59, 60 – 69 and ≥ 70.*
>
> Whereas in this current written advice following up to the May 8th TC:
>
> > *Please provide the numbers and proportions of subjects in the TVC of the main pooling for each vaccination group for the following safety outcomes by gender, ethnicity and race for the protocol pre-specified age groups (50 – 59, 60 – 69 and ≥ 70).*
>
> Our initial understanding was that CBER only required the subgroup analyses by age for gender. However, it seems now the request is for the subgroup analyses by age for all three analyses (gender, ethnicity and race).

The attached proposal considers the request received following the May 8th TC, and, therefore, the maximum number of analyses to be done. Note, the difference in the number of tables to be generated for these two requests is 84 tables (April 28th) versus 168 tables (May 8th).

Do not hesitate to contact me with any questions related to this proposal. We would be happy to discuss the contents of the packages and timings with CBER at your earliest convenience. GSK looks forward to the Agency's feedback.

Thank you and kind regards,

Jody

Please note my new mobile number

Jody Ann Gould, PhD
Head, US Policy & Intelligence and Business Excellence
US Lead Zoster
North American Regulatory Affairs, Vaccines

GSK
709 Swedeland Road, King of Prussia, PA 19406, United States
Email jody.a.gould@gsk.com
Tel (office) **+** 1 610 917 2985
Tel (mobile) + 1 267 535 0301