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-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	IR regarding safety results for IND and non-IND clinical studies containing the ASO1B adjuvant system
FDA Participants	Mike Smith, Ram Naik and Carmen Collazo
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body:

See e-mail chain below.

RECORD OF TELEPHONE CONVERSATION

From: Jody Gould [mailto:jody.a.gould@gsk.com]
Sent: Wednesday, July 05, 2017 10:13 AM
To: Smith, Michael (CBER)
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
Importance: High

Hi, Mike,

This message outlines GSK's plan to respond to this IR, so that we can be sure we are addressing the request.

To respond to your IR, GSK plans to provide the following information (tabulated listing), for studies of AS01B-containing vaccines, other than Shingrix:

- **Study #/title**
- **Patient population**
- **Number of subjects exposed to the AS01B-containing vaccine (GSK sponsored and completed studies, other than Shingrix)**
- **Study safety conclusions (extracted from CSR – synopsis)**

Please note that this information will be provided only for studies of vaccines containing AS01B, and not other formulations with the same components (e.g., AS01E, including the malaria vaccine for children, Mosquirix). Also, note that only completed studies will be included in this tabulation.

The available results of completed studies of Shingrix in older adults, and of on-going studies of Shingrix in immunocompromized subjects (Zoster -001 and -015) are described in detail in the BLA. We will provide cross-references in our response.

GSK proposes to submit the requested information with the response to the June 30th IR, *by July 21st*.

Please advise if this proposal describes the information CBER is looking for, and if the proposed timeline is acceptable.

Thanks!

Jody

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

GSK
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From: Smith, Michael (CBER) [mailto:Michael.Smith2@fda.hhs.gov]
Sent: Monday, July 03, 2017 10:40 AM
To: Jody Gould; Norris Pyle
Cc: Collazo, Carmen; Naik, Ramachandra
Subject: STN 125614/0: IR regarding safety results for IND and non-IND clinical studies containing the ASO1B adjuvant system

EXTERNAL

Jody and Norris,

Please provide, or indicate where we can find in the BLA submission, information regarding IND and non-IND clinical studies of products containing the AS01B adjuvant system, with a brief summary of pertinent safety results. A tabular summary of these studies and the relevant findings would be appreciated. Please submit your response as an amendment to the BLA within one week of receipt of this request.

Regards,

Mike

- Please confirm receipt of this IR and also let us know when you anticipate responding to it.

Mike Smith, Ph.D.
Captain, United States Public Health Service
Senior Regulatory Reviewer
United States Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review

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