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	29-SEP-2017 08:13 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	AD - Advice
Telecon Summary	CBER comments regarding Pharmacovigilance Plan submitted in amendment 47
FDA Participants	Ramachandra Naik and Carmen Collazo-Custodio
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: IR e-mail message pasted below.

RECORD OF TELEPHONE CONVERSATION

From: Naik, Ramachandra
Sent: Friday, September 29, 2017 8:13 PM
To: 'Jody Gould' <jody.a.gould@gsk.com>
Cc: Norris Pyle <norris.h.pyle@gsk.com>; Collazo, Carmen <Carmen.Collazo@fda.hhs.gov>
Subject: STN 125614/0 Shingrix BLA: CBER comments on Pharmacovigilance Plan

Dear Dr. Gould:

Our review of the information provided in your BLA dated October 21, 2016, for Zoster Vaccine Recombinant, Adjuvanted, is ongoing. We have the following comments regarding your Pharmacovigilance Plan submitted in sequence 0047, dated September 26, 2017:

1. The ocular complication risk should be described in a manner that adequately reflects the imbalances observed in the clinical trial data, while being adequately sensitive to identify cases of concern. We request that you amend the description of the risk of ocular complications so that it identifies "optic ischemic neuropathy (OIN)" in general, and not "arteritic optic ischemic neuropathy" only. This is because the imbalance in the clinical trial data was based on OIN cases, and coding systems such as MedDRA (at the preferred term [PT] level) and ICD-10 do not adequately differentiate between arteritic and non-arteritic types.

2. In addition to clinical judgement, the lists of MedDRA PTs will aid the identification of cases. As such, the PTs should include pathology related to the complications of concern. We request that you add "temporal arteritis" to Table 2, "List of MedDRA PTs (in MedDRA version 20.0) to identify cases of: serious ocular complications that may be due to vasculitis or inflammation."

3. We previously conveyed that conditions such as OIN should be identified in the appropriate "risk" section of the PVP. OIN was moved to the "Ocular complications" section, but "temporal arteritis" remained in the pIMD section. We request that you move "temporal arteritis" to the ocular complication section.

Please provide your responses to this Information Request by October 6, 2017, in an Amendment to STN 125614/0. We recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference.

Please confirm receipt of this message. If you have any questions about this communication, please contact Ramachandra Naik, Ph.D. at (301) 796-2640.

Regards,

RECORD OF TELEPHONE CONVERSATION

Ram

Ramachandra S. Naik, Ph.D.
Chemist (Regulatory) / Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
ramachandra.naik@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.