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	02-AUG-2017 03:47 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	Clinical IR regarding adding 'overall' totals column to tables
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould, Norris Pyle and Linda Kramer

Telecon Body: IR e-mail message pasted below.

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From: Naik, Ramachandra
Sent: Wednesday, August 02, 2017 3:47 PM
To: 'Jody Gould'
Cc: Collazo, Carmen; Smith, Michael (CBER); 'Norris Pyle'; 'Linda Kramer'
Subject: STN 125614/0: Clinical IR regarding adding 'overall' totals column to tables

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 request for additional information:

1. With regard to the submission in amendment 29 (dated July 12, 2017), please revise the following summary tables to include a totals column (all ages, i.e., "overall") with the proportions of subjects in each vaccination group (TVC, main pooling) by race, ethnicity and gender who experienced the event of interest during the specified time period:
   Tables 2 – 7 and Tables 16 – 20.

2. Please also provide similar tables for the proportions of subjects overall in each vaccination group (TVC, main pooling) by race, ethnicity and gender:
   (a) who died during the whole post-vaccination period
   (b) who reported at least once the occurrence of a pIMD during the whole post-vaccination period.

Please provide your responses, in an amendment to STN 125614/0, by Wednesday, August 9, 2017.

Please confirm receipt of this message, and let us know if you have any questions or need additional information.
Regards,
Ram

Ramachandra S Naik, Ph.D.
Primary Reviewer/Regulatory Project Manager
Food and Drug Administration
CBER/OVRR/DVRPA/RRB3
10903 New Hampshire Avenue
Building 71, Room 3045
Silver Spring, MD 20993
Phone: (301) 796-2640
FAX: (301) 595-1244

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