

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125614/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	GlaxoSmithKline Biologicals / Lic. # 1617
<b>Product</b>	Zoster Vaccine Recombinant, Adjuvanted

## Telecon Details

<b>Telecon Date/Time</b>	08-MAY-2017 12:00 PM
<b>Author</b>	NAIK, RAMACHANDRA
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	AD - Advice
<b>Telecon Summary</b>	CBER advised GSK what tables and data/information need to be redone.
<b>FDA Participants</b>	Paula Agger Carmen Collazo-Custodio Meghan Ferris Andrea Hulse Ramachandra Naik Keith Peden Elizabeth Sutkowski
<b>Applicant Participants</b>	Jody Ann Gould, Senior Director, North American Regulatory Affairs, Vaccines Marie-Pierre David, Senior Manager, Biostatistics Lidia Oostvogels, Director, Clinical and Epidemiology Project Leader Herpes Zoster Vaccine, Clinical RDC Belgium Tamzin Tanner, Senior Manager, Global Regulatory Affairs Fernanda Tavares, Director, Head of Safety Evaluation and Risk Management Toufik Zahaf, Senior Manager, Lead Statistician Herpes Zoster Vaccine

### Background:

During the May 3, 2017, Mid-Cycle Communication, CBER indicated that we will provide GSK specific information regarding what tables and data/information should be reanalyzed and resubmit. Later, a follow-up teleconference with GSK for May 8, 2017, at 12:00 PM was scheduled for this discussion.

### Telecon Body:

CBER stated that we have highlighted the tables in the "Demography Post-Text Tables" document for studies Zoster-006 and Zoster-022 that we don't need GSK to revise. This method applies to all other studies. These marked documents will be provided to GSK along with request for other information/analyses. GSK asked if this method applies

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global summaries also. CBER replied that it does not apply to entire safety. It is acceptable as long as the proportions are found elsewhere.

CBER asked if safety analyses were performed by gender, race and ethnicity. GSK replied that they weren't. CBER asked them to perform such analysis for studies Zoster-006, Zoster-022 and in TVC of the main pooling for the protocol pre-specified age groups (50-59, 60-69 and  $\geq 70$ ). Additional details will be provided to GSK later as post-meeting note.

Regarding ethnicity, GSK asked if 90% is American Hispanic or Latino and 10% Not American Hispanic or Latino, is acceptable to CBER. CBER indicated that it is acceptable, and added that we also agree if 15% subjects are of "others combined" including Asians.

CBER stated that in our post-meeting note, we will also include request for analysis on vaccine efficacy. GSK agreed.

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