

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	12-OCT-2017 05:26 PM
Author	COLLAZO-CUSTODIO, CARMEN
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	Agreed upon draft PMC's for GSK to verify and then officially submit to the BLA.
FDA Participants	Carmen Collazo, Ram Naik and Mike Smith
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: See e-mail below.

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From: Collazo, Carmen

Sent: Thursday, October 12, 2017 5:26 PM

To: Jody Gould (jody.a.gould@gsk.com) <jody.a.gould@gsk.com>

Cc: Norris Pyle (norris.h.pyle@gsk.com) <norris.h.pyle@gsk.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>

Subject: STN 125614/0, SHINGRIX Postmarketing Commitments

Importance: High

Sensitivity: Confidential

Dear Dr. Gould,

Please provide an amendment to the BLA by **Monday, October 16, 2017**, outlining your postmarketing commitments to conduct the studies as outlined below:

1. Study Zoster-062 to assess the safety, reactogenicity, and immunogenicity of SHINGRIX in adults ≥ 50 years of age with a prior episode of Herpes Zoster.

Final protocol submission: June 30, 2018

Study completion: November 30, 2020

Final Report Submission: November 30, 2021

2. A targeted safety study, EPI-ZOSTER-030 VS, to evaluate the safety of SHINGRIX in adults ≥ 50 years of age in real life settings in the United States.

Final protocol submission: January 30, 2019

Study completion: June 30, 2024

Final Report Submission: March 30, 2025

3. Study Zoster-049 to assess the long-term efficacy, immunogenicity, and safety of SHINGRIX in adults ≥ 50 years of age.

Final protocol submission: December 18, 2015

Study completion: July 28, 2023

Final Report Submission: May 25, 2024

Thank you so much!

Carmen