

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	23-JAN-2017 12:36 PM
Author	NAIK, RAMACHANDRA
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	PNA - PNR Acceptance
Related STNs	None
Related PMCs	None
Telecon Summary	CBER informed GSK that their proposed proprietary name, SHINGRIX, for the Zoster Vaccine Recombinant, Adjuvanted, is acceptable.
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: E-message pasted below.

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From: Naik, Ramachandra

Sent: Monday, January 23, 2017 12:36 PM

To: 'Jody Gould'

Cc: Norris Pyle; Smith, Michael (CBER); Collazo, Carmen

Subject: STN 125614/0, Shingrix BLA: Proprietary Name Acceptable

Dear Dr. Gould,

We have reviewed your November 4, 2016, submission to your Biologics License Application (BLA) for Zoster Vaccine Recombinant, Adjuvanted, requesting a proprietary name review for SHINGRIX.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, SHINGRIX, is acceptable.

Please confirm receipt of this message, and let me 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

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