

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.0
Review Office	OVRR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	22-SEP-2017 02:15 PM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Advice on the use of hazard ratio in the pharmacovigilance study
FDA Participants	Sudhakar Agnihothram, OVRR, DVRPA.
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs.

Telecon Body: From: Agnihothram, Sudhakar

Sent: Friday, September 22, 2017 6:28 PM

To: Elaine Alambra <EAlambra@dynavax.com>

Cc: Berkousen, Katherine <Katherine.Berkousen@fda.hhs.gov>; Daemer, Richard J. <Richard.Daemer@fda.hhs.gov>

Subject: ** STN 125428 - Follow-up clarification on the issue discussed during 9/21/17 Telecon**

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Hi Elaine,

As a follow up to 9/21/17 telecon, please find our comments on the Hazard Ratio (HR) as stated below.

FDA agrees with your proposal to use a HR of 2.5 for the interim results as threshold to conduct formal analyses.

On a different note, please note we are still reviewing your synopsis for the Post Marketing Study DV-HBV -26, as well as your submission STN 125428/0/93 describing details of the pregnancy registry.

Within next two weeks, we will be providing you with our comments on both of these submissions.

Thanks,

Sudhakar

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