

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

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

## Telecon Details

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