

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125428/0.0
<b>Review Office</b>	OVRR
<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>	20-SEP-2017 01:12 PM
<b>Author</b>	AGNIHOTHAM, SUDHAKAR
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	No
<b>Communication Categories</b>	AD - Advice
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Email Granting the telecon for 91517 as requested by Dynavax
<b>FDA Participants</b>	Sudhakar Agnihothram, Richard Daemer and Katherine Berkousen
<b>Applicant Participants</b>	Elaine Alambra, Senior Director, Regulatory Affairs

### Telecon Body:

**From:** Agnihothram, Sudhakar

**Sent:** Wednesday, September 20, 2017 10:50 AM

**To:** Elaine Alambra <EAlambra@dynavax.com>

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

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<Richard.Daemer@fda.hhs.gov>

**Subject:** RE: HEPLISAV BLA 125428: Proposed telecom re postmarketing study synopsis / Status request

Hi Elaine,

As requested by Dynavax, CBER has granted a teleconference to discuss the post marketing study synopsis. The timing will be 3PM to 5 PM EST.

I will send you the call in number.

Regarding the IN process testing, we are still discussing the issue internally. We will get back to you as soon as a decision is being made.

Thanks,

Sudhakar