

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	20-SEP-2017 01:12 PM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Email Granting the telecon for 91517 as requested by Dynavax
FDA Participants	Sudhakar Agnihothram, Richard Daemer and Katherine Berkousen
Applicant Participants	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