

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	31-JUL-2017 03:00 AM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	IR conveying Dynavax about a telecon to discuss PVP issues
FDA Participants	Sudhakar Agnihothram
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body: From: Agnihothram, Sudhakar

Sent: Monday, July 31, 2017 7:28 PM

To: Elaine Alambra <EAlambra@dynavax.com>; Berkhousen, Katherine
<Katherine.Berkhousen@fda.hhs.gov>

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

Subject: RE: HEPLISAV BLA 125428 / Thank You and Follow-Up

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Hi Elaine,

The purpose of tomorrow`s call is to discuss the requirement of additional information on your proposed pharmacovigilance plan.

Thanks and please let us know if you have any further questions.

Sudhakar