

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	08-AUG-2017 02:55 AM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	IR requesting Dynavax to submit a revised PVP Prior to August 10
FDA Participants	[Entered by the user, not system generated.]
Applicant Participants	[Entered by the user, not system generated.]

Telecon Body: From: Agnihothram, Sudhakar

Sent: Tuesday, August 08, 2017 2:55 PM

To: Elaine Alambra <EAlambra@dynavax.com>

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

Subject: Important information regarding : STN 125428/0 Request For Further

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Information

Importance: High

Dear Elaine,

We are writing to follow up on the submission of your response to the Information Request for the revised pharmacovigilance plan, as was sent to you on August 2nd, 2017, and acknowledged by you. As noted below we need your response **prior to August 10, 2017.**

Katherine Berkhausen also left a voice-mail yesterday on your cell phone to follow up, and we are waiting to hear from you.

Thanks and your prompt response to this is appreciated.

Sudhakar