

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

## RECORD OF TELEPHONE CONVERSATION

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 2<sup>nd</sup>, 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