

# 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>	05-OCT-2017 03:10 AM
<b>Author</b>	AGNIHOTHRAM, SUDHAKAR
<b>EDR</b>	No
<b>Post to Web</b>	No
<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 requesting a teleconference to discuss issues related to data quality and statistical plans
<b>FDA Participants</b>	Sudhakar Agnihothram, DVRPA/OVRR
<b>Applicant Participants</b>	Elaine Alambra, Senior Director Regulatory Affairs

**Telecon Body: From:** Agnihothram, Sudhakar

**Sent:** Thursday, October 05, 2017 3:10 PM

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

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

**Subject:** STN 125428/102 - Teleconference at 4:30 Pm EST today

**Importance:** High

## RECORD OF TELEPHONE CONVERSATION

Dear Elaine,

CBER would like to hold a teleconference with you to obtain some clarification on issues related to Data Quality and Statistical Plans for the Pharmacovigilance Study DV-HBV 25, as proposed in the recent synopsis that was submitted.

Please have your statistical team and the pharmacovigilance team on call , and anyone else from your team that you may feel appropriate.

We prefer to hold this telecon at 4:30 PM EST today, 10/05/17.

We will send you the call information.

Please confirm the receipt of this phone call at the earliest.

Thanks,

Sudhakar

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