

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	05-OCT-2017 03:10 AM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Email requesting a teleconference to discuss issues related to data quality and statistical plans
FDA Participants	Sudhakar Agnihothram, DVRPA/OVRR
Applicant Participants	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: Berkousen, Katherine <Katherine.Berkousen@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

Sudhakar Agnihothram B.Pharm, Ph.D,
Primary Reviewer/ Regulatory Project Manager,
Division of Vaccine Related Product Applications,
Office of Vaccines Research and Review,
Center For Biologics Evaluation and Research,
10903, New Hampshire Avenue,
BLDG 71, 3215 C,
Silver Spring, Maryland, 20993.
Email: Sudhakar.Agnihothram@fda.hhs.gov
Ph: 301-348-3056