

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	23-AUG-2017 11:36 AM
Author	AGNIHOTHRAM, 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	Question on Timeline of Submission of PVP
FDA Participants	Sudhakar Agnihothram, OVRR, DVRPA
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar

Sent: Wednesday, August 23, 2017 11:36 AM

To: Elaine Alambra <EAlambra@dynavax.com>

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

Subject: STN 125428/0 : Question on the Time Line of Submission

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Dear Elaine,

As a follow up to our clarification, please confirm that you are still on the target timeline to submit a detailed synopsis of your revised Pharmacovigilance Plan by the end of

August.

Thanks,

Sudhakar