

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	16-AUG-2017 03:49 PM
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	An IR requesting the source of information (specific BLA sections) for the clinical data listed in Sections 6, 8 and 14 of the proposed label.
FDA Participants	Sudhakar Agnihothram, Richard Daemer and Katherine Berkhausen
Applicant Participants	Elaine Alambra, Senior Director Regulatory Affairs

Telecon Body: From: Agnihothram, Sudhakar
Sent: Wednesday, August 16, 2017 3:49 PM
To: 'Elaine Alambra'
Cc: Daemer, Richard J.; Berkhausen, Katherine
Subject: STN 125428/0 Request For Further Information

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Dear Elaine,

Please provide the source of information (specific BLA sections) for the clinical data listed in Sections 6, 8 and 14 of the proposed label.

Thanks,

Sudhakar

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