

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	17-JUL-2017 12:47 PM
Author	AGNIHOTHARAM, 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 clarification on Dynavax`s response to the IR dated 5/11/17.
FDA Participants	Sudhakar Agnihothram
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar

Sent: Monday, July 17, 2017 12:47 PM

To: 'Elaine Alambra'

Cc: Berkhausen, Katherine; Daemer, Richard J.

Subject: Follow up regarding your response to IR dated 5/11/17

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Hi Elaine,

I am writing to follow up on your response submitted to the IR dated 05/11/2017. The response document is attached. In response to Item # 2, you had indicated that you will provide the requested information on Subject 128-042 (as identified in CR Item # 26) as soon as the clinical trial site responds. Please let us know when you plan to submit this information.

Thanks, Sudhakar

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