

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	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 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 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

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