

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	11-MAY-2017 10:40 AM
Author	Darcie Everett
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	Email IR from Clinical Team requesting more details on adjudication of MACE events
FDA Participants	Sudhakar Agnihothram, Richard Daemer and Katherine Berkousen. RPMs - OVRR/DVRPA
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs.

Telecon Body:

From: Agnihothram, Sudhakar
Sent: Thursday, May 11, 2017 10:40 AM
To: 'Elaine Alambra'

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Cc: Berkhausen, Katherine; Daemer, Richard J.

Subject: Information Request Re: STN 125428. 0

Dear Elaine,

Please find our request for information. Please provide your response by **COB 5/18/17**.

1. With regard to your response to CR item 2, submitted on October 3, 2016, we acknowledge your major adverse cardiovascular events analysis. Please submit the instructions provided to adjudicators regarding the categorization of events as 1) a MACE event, 2) not a MACE event, or 3) insufficient information to make a determination. If adjudicators followed standardized definitions for categorizing events, please provide those definitions.

2. Regarding your response to CR item 26. We note that subject 125-428 in Study DV2-HBV-23, who reported a non-serious MAE of MI 112 days following the first injection of HEPLISAV of one day duration, had an abnormal EKG and an abnormal nuclear perfusion scan indicating a “small inferior wall infarction with a small area of ischemia” as per the cardiologist. In the consultation, the cardiologist notes that he or she has “no old tracings.” Please confirm that there were no EKGs or other cardiac evaluations for this subject performed from the time of study enrollment to September 23, 2014, the date of the abnormal nuclear imaging.

Thanks ,

Sudhakar

Sudhakar Agnihothram B.Pharm, Ph.D,

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