

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	02-AUG-2017 01:56 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 Dynavax to submit revised PVP addressing all of the concerns raised by VRBPAC on July 28th.
FDA Participants	Sudhakar Agnihothram, Katherine Berkhausen and Richard Daemer
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar

Sent: Wednesday, August 02, 2017 1:40 PM

To: 'Elaine Alambra'

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Cc: Berkhousen, Katherine; Daemer, Richard J.

Subject: STN 125428/0 Request For Further Information

Dear Elaine,

Please find our request for further information as discussed during the telecon yesterday.

1. We consider your current plan to evaluate acute myocardial infarction in a post-marketing study to be inadequate. Please provide a draft synopsis of a post-marketing study to evaluate acute myocardial infarction, taking into account the feedback obtained from the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) on July 28, 2017. Please provide an initial draft synopsis prior to the action due date of August 10, 2017.

Your proposed plan should address elements that the VRBPAC deemed critically important, including, but not limited to:

- a) measures to ensure comparability of study arms, particularly with regard to cardiovascular risk factors (minimization of selection bias)
 - b) timeliness of recruitment
 - c) timeliness of evaluations including interim assessments that would allow early detection of a potential imbalance in acute MI between groups and availability of those results to CBER
 - d) provisions for further evaluation and potential pausing or discontinuation of the study if interim assessments identify an imbalance in acute MI between groups
 - e) timeliness in obtaining final study results
 - f) need for an event-driven study (recruitment stops only when the required number of acute myocardial infarction events have been reached)
 - g) appropriate statistical power
2. For a post-marketing study to evaluate acute myocardial infarction, please provide dates for the following milestones:
 - a) final protocol submission
 - b) study completion
 - c) final report submission.
 3. Please provide an update on your plans for post-marketing evaluation of immune mediated diseases and herpes zoster.
 4. Please address what efforts you have made and what additional plans, if any, you may have to obtain clinical information on subjects lost to follow-up in Study HBV-23.

We look forward to hearing back from you.

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Thanks,

Sudhakar

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