

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125428/0.0
<b>Review Office</b>	OVR
<b>Applicant</b>	Dynavax Technologies Corporation / Lic. # 1883
<b>Product</b>	Hepatitis B Vaccine (Recombinant), Adjuvanted
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	02-AUG-2017 01:56 PM
<b>Author</b>	AGNIHOTHAM, SUDHAKAR
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	An IR requesting Dynavax to submit revised PVP addressing all of the concerns raised by VRBPAC on July 28th.
<b>FDA Participants</b>	Sudhakar Agnihothram, Katherine Berkousen and Richard Daemer
<b>Applicant Participants</b>	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:** Berkhausen, 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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