

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	24-APR-2017 10:32 AM
Author	Everett, Darcie
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Clinical IR, regarding CRL item#12, and request for specific clarification and the CRF of a specific subjects.
FDA Participants	Katherine Berkousen; Richard Daemer
Applicant Participants	Elaine Alambra

Telecon Body:

From: Elaine Alambra [mailto:EAlambra@dynavax.com]

Sent: Monday, April 24, 2017 1:39 PM

To: Berkousen, Katherine

Cc: Daemer, Richard J.; Agnihothram, Sudhakar

Subject: RE: IR for 125428.0- Clinical

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Dear Katherine,

Acknowledge receipt.

Kind regards,

Elaine

Elaine Alambra • Senior Director, Regulatory Affairs • Dynavax Technologies Corporation (Tel: 510-665-0474 * email: ealambra@dynavax.com)

From: Berkhousen, Katherine [<mailto:Katherine.Berkhousen@fda.hhs.gov>]

Sent: Monday, April 24, 2017 10:32 AM

To: Elaine Alambra

Cc: Daemer, Richard J.; Agnihothram, Sudhakar; Berkhousen, Katherine

Subject: IR for 125428.0- Clinical

Dear Elaine,

We have the following information request:

1. We have the following requests regarding the Dynavax response to CRL Item # 12:
 - a. Please clarify, who was responsible for referring lost-to-follow-up subjects to the vendor, (b) (4), for reengagement? For example, did the study sites (without input from Dynavax or the monitor), Dynavax, the monitor, or a combination of the above entities, refer subjects to the vendor?
 - a. Please provide a list of subjects who were lost-to-follow-up and not referred to the vendor for re-engagement. In this list please include subject number, subject treatment assignment, visit number and date subject was first determined to be lost-to-follow-up, and reason the subject was not referred (reason 1 versus reason 2 in your response to comment 12).

The following requests refer to subjects in DV2-HBV-23:

2. Subject 136-022 reported “allergic reaction,” preferred term Hypersensitivity, on Study Day 1, which was treated with epinephrine, diphenhydramine (oral and intravenous (IV)), methylprednisolone (IV), famotidine (IV), and prednisone, and assessed as Grade 2 and probably related.

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- a. Please provide a narrative and CRFs for this subject.
 - b. Please also provide the rationale for why this event was not reported as anaphylaxis and why it was not determined to be serious.
3. Please provide a narrative and CRFs for Subject 134-342, who reported the non-serious MAEs of throat tightness and urticaria on Study Day 1, for which study treatment was discontinued.
 4. Subject 130-219 reported an SAE of end stage renal failure (ESRD) on Day 10 following Dose 2 of Heplisav. In your response to comment 11b of the CR letter, the narrative provided states the subject had chronic kidney disease (CKD) at baseline. Please provide additional information regarding the etiology and progression of this event. Specifically, please provide the stage of the subjects CKD at baseline, the etiology of the CKD/ESRD, and any supporting laboratory results from prior to study enrollment through the onset of the event.

Kind regards,

Katherine

Katherine Berkousen
CAPT., US Public Health Service

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