

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-2016 12:37 PM
Author	CHOUDHARY, ANIL
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	IR having to do with in vivo potency assay and document submitted in the July 28, 2016 submission
FDA Participants	Katherine Berkousen
Applicant Participants	Elaine Alambra

Telecon Body:

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

Sent: Tuesday, August 02, 2016 12:37 PM

To: Berkousen, Katherine

Subject: RE: IR - in vivo potency assay and documents

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Dear Katherine,

Acknowledged receipt.

Thanks,

Elaine

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

Sent: Tuesday, August 02, 2016 9:17 AM

To: Elaine Alambra

Cc: Berkhausen, Katherine

Subject: IR - in vivo potency assay and documents

Dear Elaine,

We continue to review your licensing application BLA 125428. We have the following requests related to the in vivo potency assay and the documents you submitted on July 28, 2016 in response to our IR dated 24 May, 2016.

1. In document DUS SOP QC 113-07: In vivo Potency Assay Part 1: Vaccine Dilution Prep- Section 6 (Procedure) on page 12- states that, “ (b) (4)
 (b) (4)
 (b) (4)
 a. Please provide DUS-SOP-L-SOP 237 (b) (4) In-
 vivo potency determination) and the SOFTWARE- (b) (4) .
 b. Also, please provide DUS-SOP-QC-0157 (Preparation of vaccine dilutions
 from Heplisav (b) (4) or vials), in English translated format.
 c. Please let us know any differences in processing of Heplisav samples –
 between (b) (4) and vials- for performing in-vivo potency test, as per
 DUS-SOP-QC-0157.
2. In document DUS SOP QC089-09 -Please provide all the validated Excel
 sheet (Annexure 1, 4 and 6) mentioned in section 6.4 (Evaluation) and section 7.2
 - for calculation of seroconversion cut off, outlier calculation and other related
 validated calculation excel sheets.
3. Please provide the qualified working range for using the following reagents (not
 reported in the COAs):

(b) (4)

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4. Please provide the concentration for (not reported in the COAs):

- a. Anti-HBsAg Standard for (b) (4) (Lot# (b) (4))- sample ID (b) (4)
- b. Anti-HBsAg Standard for (b) (4) (Lot# (b) (4)) sample ID (b) (4)

Kind regards,

Katherine

Katherine Berkhausen
CAPT., US Public Health Service

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