

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-SEP-2016 04:40 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	Repeat of the 8/2/16 IR and request to hold telecon
FDA Participants	Katherine Berkousen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkousen, Katherine
Sent: Friday, September 02, 2016 4:40 PM
To: Alambra, Elaine
Cc: Daemer, Richard J.
Subject: follow up to the August 2nd IR

RECORD OF TELEPHONE CONVERSATION

Dear Elaine,

We have the following request. Please note that the below items were requested in our August 2, 2016 information request and have not yet been addressed. It is important that we receive the requested information and the actual (b) (4) Software ASAP. We would like to suggest a teleconference next week with the appropriate people to discuss any potential problems that Dynavax may be encountering in responding to this request. We would be available on Tues or Wed morning.

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)
 - a. Please provide DUS-SOP-L-SOP 237 (Software (b) (4) (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. Please provide the qualified working range for using the following reagents (not reported in the COAs):
(b) (4)
(b) (4)

3. Please provide the concentration for (not reported in the COAs):
 - a. Anti-HBsAg Standard for (b) (4) (Lot# (b) (4))- sample ID (b) (4),

RECORD OF TELEPHONE CONVERSATION

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

Kind regards,

Katherine

Katherine Berkousen
CAPT., US Public Health Service

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