

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	06-APR-2017 02:51 PM
Author	Kenney, James
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	Email request to hold telecom to clear up the discrepancies regarding the (b) (4) endotoxin support testing differences using the (b) (4) method validation/qualification
FDA Participants	Katherine Berkousen; Sudhakar Agnihothram
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkousen, Katherine

Sent: Thursday, April 06, 2017 2:51 PM

To: Alambra, Elaine

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

Subject: Telecon Request reg Endotoxin support testing of conformance lots

Dear Elaine,

CBER performed (b) (4) endotoxin licensing support testing of the Heplisav conformance lots submitted in support of your license application. The samples were tested per your (b) (4) method validation/qualification report at a (b) (4) sample dilution using the same (b) (4) reagent kit. CBER experienced more product enhancement of the positive product control than reported in your laboratory. This disparity in method qualification criteria could delay or prevent the release of product lots post licensing. Therefore, CBER requests a teleconference with those who performed sample testing for the (b) (4) method validation report to determine if there are subtle difference between our methods that could explain the observed differences in positive product control recovery.

Below are the results for comparison. On average, CBER is getting 50% more product enhancement of the PPC. Of the lots tested, Lot 1033385 was the most recent lot produced and provided the most product enhancement. The second table below provides results tested at the maximum valid testing dilution (i.e., (b) (4)) and even though lot 1033385 passed, our PPC % recovery ((b) (4)) was still higher than yours (b) (4) tested at (b) (4). Indicating there is a possibility CBER could reject a lot for release, even though it passed your lot release testing. Thus, the main reason for this teleconference request.

(b) (4) test results at sample dilution of (b) (4)

Lot Number	Test Dilution	CBER		Dynavax [†]	
		% Spike Recovery**	Results (b) (4)	% Spike Recovery	Results ((b) (4))
1033385	(b) (4)				
1017099					
1017100					

[†] Amendment 125428/0/74 dated February 7, 2017

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(b) (4) test results at sample dilution of (b) (4) (CBER's additional data)

Lot Number	Test Dilution	% Spike Recovery**	Results (b) (4)
1033385	(b) (4)		
1017099			
1017100			

We request a telecon with Dynavax to further discuss. We would be available next Wed April 12th at 11:00 EST.

Kind regards,

Katherine

Katherine Berkhausen
CAPT., US Public Health Service

FDA/CBER/Office of Vaccines
Div. of Vaccines & Related Products Applications
10903 New Hampshire Ave. WO71-3022
Silver Spring, MD 20993-0002

Tel: (301) 796-1296