

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	18-JUL-2016 02:28 PM
Author	BHATTACHARYYA, LOKESH
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 regarding Method Validation
FDA Participants	Katherine Berkhousen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkhousen, Katherine
Sent: Monday, July 18, 2016 2:48 PM
To: Alambra, Elaine
Cc: Berkhousen, Katherine; Daemer, Richard J.
Subject: 125428 IR - Method Validation

RECORD OF TELEPHONE CONVERSATION

Dear Elaine,

We have reviewed the information submitted to your BLA 125428/0/48, (Sequence # 46) on 5/16/2016, regarding the (b) (4) assay method, method validation protocol and validation report; and have the below listed requests. We request that you provide a response within 2 weeks; if that is not possible, please give us a date by which we can expect a response.

1. Method:

- a. Please provide description of the method, including (b) (4) (b) (4), etc.) and assay acceptance criteria in sufficient details so that a trained analyst can follow and execute the method in our laboratory.
- b. On page 10 of 21 of "Response to 27 April 2016 Information Request" (Seq # 0046, Amendment 48), you indicated that a system suitability standard (SST) is prepared by (b) (4) (b) (4). Please explain.
- c. You (b) (4) (b) (4) is not clear to us. Please clarify.

2. Method Validation

- a. Under Accuracy in page 12 of 21 of "Response to 27 April 2016 Information Request" you used the following equation to calculate recovery:

(b) (4)

We do not think that the equation you used is correct. Please explain. You may need to recalculate your recovery data using the corrected equation. If so, please submit the recalculated results.

b. Precision:

- i. Repeatability was assessed from independent runs at the same concentration of (b) (4). Please provide repeatability assessment from (b) (4) runs at the same concentration of (b) (4) in the (b) (4) each.
- ii. You assessed intermediate precision from results obtained by (b) (4). Intermediate precision should be assessed by at the

RECORD OF TELEPHONE CONVERSATION

minimum of (b) (4) analysts on (b) (4) days and, if applicable, using different instruments. Please provide data from appropriate assessment of intermediate precision on both samples with the (b) (4) .