

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 01:15 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 for method validation r/t (b) (4) assay
FDA Participants	Katherine Berkousen; Richard Daemer
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkousen, Katherine
Sent: Friday, September 02, 2016 1:15 PM
To: Alambra, Elaine
Cc: Daemer, Richard J.; Berkousen, Katherine
Subject: IR method validation

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Dear Elaine,

We have reviewed your information submitted on July 28, 016, in Amendment 55 (Seq#53), on method validation's precision of the (b) (4) assay and have the following Information Request.

You assessed intermediate precision from results obtained by (b) (4) using (b) (4). You stated, "(b) (4) were available to assess the intermediate precision". This is not acceptable. Intermediate precision should be assessed by at the minimum of (b) (4) analysts on preferably different instruments. Please provide data from appropriate assessment of intermediate precision on both samples from the (b) (4).

Please send the requested information by September 20, 2016. If you cannot do so, please provide the date when you will submit the requested information.

Kind regards,

Katherine

Katherine Berkhausen
CAPT., US Public Health Service

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