

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.72
Review Office	OVRR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	27-FEB-2017 01:44 PM
Author	BERKHOUSEN, KATHERINE
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 timeline regarding responding validation data
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkhausen, Katherine
Sent: Monday, February 27, 2017 1:44 PM
To: Alambra, Elaine
Cc: Daemer, Richard J.; Berkhausen, Katherine
Subject: IR

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Dear Elaine,

In your recent submission (Seq No. 0072), you indicated that (1) you would perform validation study to demonstrate linearity and accuracy for (b) (4), and (2) you would provide additional data to show that the percent of the (b) (4) would not change on formulation of the drug product and would be stable in drug product, as agreed upon in the Type A meeting on 10 January 2017. Please provide your best estimated date for submission of the data.

Katherine

Katherine Berkhausen

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