

RECORD OF EMAIL 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

EMAIL Details

Telecon Date/Time	20-AUG-2014 01:56 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Instructed to submit 483 responses to the BLA
FDA Participants	Katherine Berkhusen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkhusen, Katherine
Sent: Tuesday, August 20, 2014 2:52 PM
To: Elaine Alambra
Subject: Dynavax 483 Response

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Dear Elaine,

We would like to provide feedback to you related to your submission dated June 30, 2014 (amendment #144). We note that this submission contains the Dynavax responses to the 483 facilities inspection.

Please withdraw this information from your IND and submit it to your BLA. The cover letter should be addressed to Jay Elterman and clearly state that the items address the 483 responses.

Feel free to call if you have any questions.

Katherine

Katherine Berkousen
CAPT., US Public Health Service

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