

# RECORD OF EMAIL CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125428/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Dynavax Technologies Corporation / Lic. # 1883
<b>Product</b>	Hepatitis B Vaccine (Recombinant), Adjuvanted
<b>Trans-BLA Group:</b>	No

## EMAIL Details

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

### Telecon Body:

---

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

## RECORD OF EMAIL CONVERSATION

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 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  
[katherine.berkhousen@fda.hhs.gov](mailto:katherine.berkhousen@fda.hhs.gov)