

# 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

## Telecon Details

<b>Telecon Date/Time</b>	02-DEC-2016 02:47 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>	Advice on seeking FDA telecom or meeting s/p 12/1/16 email
<b>FDA Participants</b>	Katherine Berkhausen
<b>Applicant Participants</b>	Elaine Alambra

**Telecon Body:** Dynavax left two voice mails regarding their request to have an informal telephone meeting with DVRPA to discuss various CRL items as opposed to a regulatory meeting. This request was discussed with the committee chair, branch chief and DVRPA leadership. It was decided that a regulatory meeting offered the best opportunity to provide comprehensive guidance and advice to the applicant and would ensure that the appropriate staff would be available within the regulatory timelines.

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**From:** Elaine Alambra [mailto:EAlambra@dynavax.com]  
**Sent:** Friday, December 02, 2016 5:33 PM  
**To:** Berkhousen, Katherine  
**Cc:** Daemer, Richard J.  
**Subject:** RE: Response to voice mail

Acknowledged receipt.

Thanks, Katherine.

Best,

**Elaine**

Elaine Alambra • Regulatory Affairs • Dynavax Technologies Corporation ( Tel:  
510-665-0474 \* email: [ealambra@dynavax.com](mailto:ealambra@dynavax.com)

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**From:** Berkhousen, Katherine [mailto:[Katherine.Berkhousen@fda.hhs.gov](mailto:Katherine.Berkhousen@fda.hhs.gov)]  
**Sent:** Friday, December 02, 2016 11:26 AM  
**To:** Elaine Alambra  
**Cc:** Daemer, Richard J.  
**Subject:** Response to voice mail

Dear Elaine,

We acknowledge your two voice mails regarding our Dec 1, 2016 email. We have provided you with information on how to request clarification of the CRL items. We will do our best to schedule a meeting as soon as possible after the request comes in.

Kind regards,

*Katherine*

Katherine Berkhousen  
CAPT., US Public Health Service

FDA/CBER/Office of Vaccines  
Div. of Vaccines & Related Products Applications  
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