

# RECORD OF TELEPHONE 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>	14-OCT-2016 11:59 AM
<b>Author</b>	CAMPBELL, KAREN
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	No
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	
<b>FDA Participants</b>	Katherine Berkhousen
<b>Applicant Participants</b>	Elaine Alambra

### Telecon Body:

**From:** Berkhousen, Katherine  
**Sent:** Friday, October 14, 2016 12:41 PM  
**To:** Alambra, Elaine <EAlambra@dynavax.com>  
**Cc:** Daemer, Richard J. <Richard.Daemer@fda.hhs.gov>  
**Subject:** IR regarding lot release protocol

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Dear Elaine,

- 1) In the lot release protocol template submitted on 9/28/2016, in amendment 125428/.64, we note that the incorrect address is being used for the sample custodian. Please change this to:

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Sample Custodian  
10903 New Hampshire Avenue  
WO75-

G707

Silver Spring, MD 20993-0002

- 2) Please submit an updated protocol to the BLA by October 25, 2016. Once this correction is made you may submit the lot release protocol to the sample custodian for the launch lot that was submitted.

Kind regards,

*Katherine*

Katherine Berkousen  
CAPT., US Public Health Service

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