

# 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>	02-AUG-2016 12:37 PM
<b>Author</b>	CHOUDHARY, ANIL
<b>EDR</b>	No
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	IR having to do with in vivo potency assay and document submitted in the July 28, 2016 submission
<b>FDA Participants</b>	Katherine Berkousen
<b>Applicant Participants</b>	Elaine Alambra

### Telecon Body:

**From:** Elaine Alambra [mailto:EAAlambra@dynavax.com]  
**Sent:** Tuesday, August 02, 2016 12:37 PM  
**To:** Berkousen, Katherine  
**Subject:** RE: IR - in vivo potency assay and documents



## RECORD OF TELEPHONE CONVERSATION

4. Please provide the concentration for (not reported in the COAs):

- a. Anti-HBsAg Standard for (b) (4) (Lot# (b) (4) )- sample ID (b) (4)
- b. Anti-HBsAg Standard for (b) (4) (Lot# (b) (4) ) sample ID (b) (4)

Kind regards,

*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)