

# 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>	05-AUG-2016 01:08 PM
<b>Author</b>	HULSE, ANDREA
<b>EDR</b>	No
<b>Post to Web</b>	No
<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>	CBER questions Dynavax's statement that no other datasets were affected by the erroneous dataset entries
<b>FDA Participants</b>	Katherine Berkhousen
<b>Applicant Participants</b>	Elaine Alambra

## Telecon Body:

**From:** Berkhousen, Katherine

**Sent:** Friday, August 05, 2016 1:08 PM

**To:** 'Elaine Alambra'

**Cc:** Daemer, Richard J.; Berkhousen, Katherine

**Subject:** RE: HEPLISAV BLA 125428 / 03aug2016 telecom re HBV-16 datasets

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Dear Elaine,

Regarding our 8/3/16 telephone discussion of the inconsistencies in the HBV-16 datasets submitted to CBER and your email below:

Please provide your rationale for why the proposed changes to and the subsequent errors found in the revised ADSL HBV-016 datasets would not also impact the protd.xpt dataset, which contains the flags "NIPPFLG" and "LCPFLG" in question?

Regards,  
Katherine

**From:** Elaine Alambra [<mailto:EAlambra@dynavax.com>]  
**Sent:** Thursday, August 04, 2016 11:25 AM  
**To:** Berkhausen, Katherine  
**Cc:** Daemer, Richard J.  
**Subject:** HEPLISAV BLA 125428 / 03aug2016 telecom re HBV-16 datasets

Dear Katherine,

As requested, the Dynavax participants at the 03 Aug 2016 telecom were:

### Clinical

Robert Janssen, MD  
William Heyward, MD  
Kimberly Erby

### Biostatistics

Robert Halstead  
Brit Harvey  
Biao Xing

### Regulatory

Elaine Alambra

### **HBV-16 Datasets:**

Also at this telecom, Dynavax was asked to identify any other datasets affected by changes to the HBV-16 ADSL datasets or confirm that no other HBV-16 datasets were affected. The ADSL issue we discussed at the telecom yesterday was regarding changes to per-protocol population variables values in HBV-16 that were made in ADSL.

Dynavax has reviewed HBV-16 and can confirm that no other datasets were affected.

### **Request:**

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Please provide a list of FDA participants at the 03 Aug telecom.

Thanks much,

*Elaine*

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