

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125428/0.0
<b>Review Office</b>	OVR
<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-OCT-2016 07:05 AM
<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>	CBER concurs with the Dynavax action items of the Sep30 telephone conversation regarding the revised datasets
<b>FDA Participants</b>	Katherine Berkhausen
<b>Applicant Participants</b>	Elaine Alambra

**Telecon Body:** CBER responds to the action items that Dynavax provided via email on Sep 30, 2016, regarding the telephone call to discuss the inconsistencies in the revised datasets submitted by Dynavax.

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**From:** Berkhousen, Katherine [<mailto:Katherine.Berkhousen@fda.hhs.gov>]  
**Sent:** Wednesday, October 05, 2016 7:06 AM  
**To:** Elaine Alambra  
**Cc:** Daemer, Richard J.  
**Subject:** RE: HEPLISAV BLA 125428 / FDA Telecom 30 Sep 2016

Dear Elaine,

The information you have outlined in your email captures the information we discussed.

-Katherine

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**From:** Elaine Alambra [<mailto:EAlambra@dynavax.com>]  
**Sent:** Friday, September 30, 2016 6:08 PM  
**To:** Berkhousen, Katherine  
**Cc:** Daemer, Richard J.  
**Subject:** HEPLISAV BLA 125428 / FDA Telecom 30 Sep 2016

Dear Katherine,

As discussed in our teleconference this morning regarding Item 24 (Information Request 09 Sep 2016) on the Master Dataset and Excel files, Dynavax will provide the following to the Agency:

### **Master ADSL Datasets** (response to Item **24a**)

- HBV-10 (2012 and 2016 merged)
- HBV-16 (2012 and 2016 merged) format acceptable as is including the current variables. The following changes will be incorporated:
  - Additional variable for **SUBJID** that will include the year (2012 or 2016).
    - For example, Subject 20301 will show: 20301-**2012** and 20301-**2016**
  - Two additional variables: One To indicate if a subject was included in our non-inferiority analysis and a separate variable for if the subject was included in the lot-consistency analysis

### **Excel Files** (response to Item **24b**)

- HBV-10 (2012 and 2016 merged)
  - Only 1 Worksheet (mirror of Master ADSL Dataset) which represents the Per-Protocol Population and changes between 2012 and 2016
- HBV-16 (2012 and 2016 merged)

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- A new tab/worksheet containing a mirror of Master ADSL Dataset (Excel Master File)
  - We will highlight the entire row for a subject where their Status changed from 2012 to 2016
- 2<sup>nd</sup> worksheet (extracted from the Excel Master File, subset for those subjects with changes to NIPP and/or LCPP)
  - Two additional variables: One To indicate if a subject was included in our non-inferiority analysis and a separate variable for if the subject was included in the lot-consistency analysis
- 3<sup>rd</sup> NIPP worksheet (for only those with changes to NIPP)
  - Additional variable to indicate if a subject was included in our non-inferiority analysis
- 4<sup>th</sup> LCPP worksheet for only those with changes to LCPP)
  - Additional variable to indicate if a subject was included in our lot-consistency analysis

Also, as part of our response to Item **24c**, we will provide an explanation of the methodology / logic for preparing the datasets and the excel files as well as how the number of subjects were calculated for each of the analysis populations.

Please confirm if our understanding is complete and accurate.

Kind regards,

**Elaine**

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