

# 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>	24-AUG-2016 03:49 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>	OT -
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	CBER plans on responding to the 8/22/16 email and Dr Jansenn's phone call to Dr Gruber, soon. Additionally, we do not have any specific issues to communicate regarding VRBPAC at the present but will let Dynavax know as soon as possible.
<b>FDA Participants</b>	Katherine Berkhausen; Richard Daemer
<b>Applicant Participants</b>	Elaine Alambra

### Telecon Body:

I contacted Dynavax (Elaine Alambra) to convey that CBER will respond to the 8/22/16 email and Dr Jansenn's phone call to Dr Gruber concerning the review of the HBV-23

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immunogenicity data. CBER will be holding internal meetings to discuss the issue. Additionally, CBER does not have any 'specific' concerns to share at this present time concerning the VRBPAC presentations. As Dynavax is already aware CBER typically seeks VRBPAC advice on matters of safety and effectiveness as well as the need for post-marketing studies. CBER acknowledges that Dynavax is waiting for a response to the HBV-23 immunogenicity review question and what safety concerns if any, CBER might plan to discuss at VRBPAC and we will respond as soon as is feasible.