

# 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>	01-AUG-2016 04:49 PM
<b>Author</b>	BERKHOUSEN, KATHERINE
<b>EDR</b>	No
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	510-665-0474
<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>	Notification of likelihood of a VRBPAC meeting in Nov
<b>FDA Participants</b>	Katherine Berkhausen
<b>Applicant Participants</b>	Elaine Alambra

**Telecon Body:** Elaine Alambra (Dynavax Regulatory Affairs) was notified of the following:

“Based on our review to date, we will likely need to take this to VRBPAC and we are giving you a heads-up of this”.