

# 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>	07-AUG-2017 05:00 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>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Dynavax asked when the revised postmarketing plan would be submitted.
<b>FDA Participants</b>	Katherine Berkhausen
<b>Applicant Participants</b>	Elaine Alambra

### Telecon Body:

Elaine Alambra was contacted. I left a voice mail on her cell phone stating that FDA was anticipating receiving a revised pharmacovigilance plan (PVP) as discussed in the Tues, Aug 1, 2017 phone call between CBER and Dynavax. Dynavax stated in this call that Dynavax was confident that they would be able to submit something by Friday Aug 4<sup>th</sup>. As of close-of-business on Monday Aug 7th, CBER has not received a revised PVP. I

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left a message asking Elaine Alambra to please provide CBER with a timeline of when they anticipated submitting the revised PVP.