

# 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-FEB-2013 3:30 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>	No
<b>Communication Categories</b>	AD - Advice
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Discussion with DVRPA leadership and Dynavax regarding various paths forward status post 2012 VRBPAC.
<b>FDA Participants</b>	Wellington Sun, MD; Marian Major, PhD
<b>Applicant Participants</b>	Tyler Martin, MD . W. Turner [Dynavax Tech]

### Telecon Body:

**From:** Sun, Wellington

**Sent:** Thursday, February 07, 2013 5:25 PM

**To:** Gruber, Marion

**Cc:** Major, Marian; Berkhausen, Katherine; Daemer, Richard J.; Smith, Lorie; Worobec,

## RECORD OF TELEPHONE CONVERSATION

Alexandra; Schragar, Lewis; Pandey, Rakesh

**Subject:** RE: Telecon with Tyler Martin and Bill Turner today

**Importance:** High

Marian and I reached out to Tyler Martin and Bill Turner with a telecon this afternoon. Summarized briefly:

1. I informed them that the reviews by the disciplines are undergoing supervisory review and outlined the major categories of concern with the current BLA: safety, facilities and CMC. These will be communicated to them in writing. Marian informed them we need to see new conformance lots and there were other issues remaining to be resolved with OCBQ but many of them are minor.

2. Most of the discussion revolved around clinical safety: We appreciate the clinical materials, including the imaging studies they have sent us, as well as their expert's input. However, I disagreed with his assessment that the concern with the case of cavernous sinus syndrome has been resolved. We are taking the two potential cases of autoimmune disease to our own expert consultation which is in progress. I emphasized that even in the absence of definite conclusions, we would require a larger safety database pre-licensure.

3. They asked if we would consider an indication for use of the vaccine in the chronic kidney disease population. The answer was yes, but the current BLA does not contain the information needed to support this indication and we would require further discussion on what additional information would be necessary for an application. I did acknowledge that the risk/benefit may differ in special populations.

4. I informed them that their email on revised proposed indications that resulted from our December face-to-face meeting is not considered part of the BLA because it has not been submitted as such. However, CBER did review them and did not think that they differ substantively from their current proposed indication in the BLA.

5. They asked if this means a CR. I said that we can't answer that question but that we have outlined during this call our major concerns that have not been adequately addressed by the current submission.

They concluded the call by thanking us for giving them clarity on what they now need to do.

Wellington