

# RECORD OF EMAIL 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>	05-AUG-2016 10:44 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>	No
<b>Communication Categories</b>	AD - Advice
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	CBER response to Dynavax's request regarding rational on going to VRBPAC and what the FDA focus would be.
<b>FDA Participants</b>	Katherine Berkhausen
<b>Applicant Participants</b>	Elaine Alambra

### Telecon Body:

**From:** Berkhausen, Katherine

**Sent:** Friday, August 05, 2016 10:44 AM

**To:** 'Elaine Alambra'

**Cc:** Daemer, Richard J.

**Subject:** RE: HEPLISAV BLA 125428 / VRBPAC-related Questions

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Dear Elaine,

As explained previously, our review of your resubmitted BLA is ongoing. Based on our review to date, we believe a VRBPAC will be likely and wanted to give you notification prior to it appearing in the Federal Register. We are still discussing the specific questions and these will depend on the ongoing review. You will be notified of the specific questions ahead of the VRBPAC.

Kind regards,  
Katherine

**From:** Elaine Alambra [<mailto:EAlambra@dynavax.com>]  
**Sent:** Tuesday, August 02, 2016 1:44 PM  
**To:** Berkhausen, Katherine  
**Subject:** HEPLISAV BLA 125428 / VRBPAC-related Questions  
**Importance:** High

Dear Katherine,

As you can imagine, Dynavax is very interested in the Agency's decision to take HEPLISAV back to VRBPAC. We have the following questions:

1. What is the Agency's rationale for taking HEPLISAV to VRBPAC again? Is it because of the negative safety vote at the previous VRBPAC or is there specific input that the Agency wants from VRBPAC?
2. What questions would the Agency want answered by VRBPAC? Will these be the standard questions on efficacy, safety, and a post-marketing study? Given that the *efficacy* question has already been decided at the last VRBPAC, would the question(s) be primarily on safety and the post-marketing study?
3. When should we expect the Agency to publish on their website that HEPLISAV is scheduled for the Nov VRBPAC?
4. Please confirm the November VRBPAC date will not impact PDUFA date.

Kind regards,

*Elaine*

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