

RECORD OF EMAIL CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.0
Review Office	OVRR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	05-AUG-2016 10:44 AM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	CBER response to Dynavax's request regarding rational on going to VRBPAC and what the FDA focus would be.
FDA Participants	Katherine Berkhausen
Applicant Participants	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

RECORD OF EMAIL CONVERSATION

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: elambra@dynavax.com