

RECORD OF TELEPHONE 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	24-AUG-2016 03:49 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	OT -
Related STNs	None
Related PMCs	None
Telecon Summary	CBER plans on responding to the 8/22/16 email and Dr Jansenn's phone call to Dr Gruber, soon. Additionally, we do not have any specific issues to communicate regarding VRBPAC at the present but will let Dynavax know as soon as possible.
FDA Participants	Katherine Berkhausen; Richard Daemer
Applicant Participants	Elaine Alambra

Telecon Body:

I contacted Dynavax (Elaine Alambra) to convey that CBER will respond to the 8/22/16 email and Dr Jansenn's phone call to Dr Gruber concerning the review of the HBV-23

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immunogenicity data. CBER will be holding internal meetings to discuss the issue. Additionally, CBER does not have any 'specific' concerns to share at this present time concerning the VRBPAC presentations. As Dynavax is already aware CBER typically seeks VRBPAC advice on matters of safety and effectiveness as well as the need for post-marketing studies. CBER acknowledges that Dynavax is waiting for a response to the HBV-23 immunogenicity review question and what safety concerns if any, CBER might plan to discuss at VRBPAC and we will respond as soon is feasible.