

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	01-AUG-2016 04:49 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	510-665-0474
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Notification of likelihood of a VRBPAC meeting in Nov
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body: Elaine Alambra (Dynavax Regulatory Affairs) was notified of the following:

“Based on our review to date, we will likely need to take this to VRBPAC and we are giving you a heads-up of this”.