

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	07-AUG-2017 05:00 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Dynavax asked when the revised postmarketing plan would be submitted.
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body:

Elaine Alambra was contacted. I left a voice mail on her cell phone stating that FDA was anticipating receiving a revised pharmacovigilance plan (PVP) as discussed in the Tues, Aug 1, 2017 phone call between CBER and Dynavax. Dynavax stated in this call that Dynavax was confident that they would be able to submit something by Friday Aug 4th. As of close-of-business on Monday Aug 7th, CBER has not received a revised PVP. I

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left a message asking Elaine Alambra to please provide CBER with a timeline of when they anticipated submitting the revised PVP.