

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	04-OCT-2016 11:07 AM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Answered questions about lot release protocol and subsequent lots for launch
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body: On Oct 3, 2016, Elaine Alambra left a voice mail for Karen Campbell asking about the results of the in-process testing of the lots that Dynavax submitted. Of the three submitted lots, one is being used for launch. I called Elaine today and told her that CBER will inform Dynavax if we have any concerns/ problems, but at this time, we do not anticipate any problems. I also reminded her that we need the final lot release protocol at least 6 weeks prior to the action due date (ADD).

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Elaine stated that Dynavax has subsequent lots that they would like to release at ADD. I stated that Dynavax would need to submit these lots at least 8 weeks prior to the ADD so that all the testing would be completed in time.

Elaine asked how they could submit the subsequent lots at 8 weeks prior to ADD without the completed lot release protocol. I stated that everything is based on receiving samples in a timely way and getting the completed final lot release protocol back to CBER. We agreed to stay in communication regarding this issue.

Elaine also asked for feedback regarding Friday, Sep 30, 2016 teleconference. I stated that once I heard back from the review team, that I would convey a response to her concerns.

This concluded the call.