

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-SEP-2016 04:03 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Telecon to clarify the CBER needs of IR 9/2/16 - the COAs should be updated to include concentration as per the IR.
FDA Participants	Katherine Berkhausen
Applicant Participants	Anil Choudhary

Telecon Body: Elaine Alambra (Dynavax) contacted to clarify some points of the CBER IR dated 9/2/16. Dynavax clarified that they do not have a (b) (4) license available that can easily be provided to CBER. Dynavax asked if CBER could use a free trial version of the (b) (4) software which is good for 30 days, free of charge and without any obligations. According to the advertisement, CBER would be able to enter data, use all settings, carry out complete evaluations and generate reports. The only thing that CBER

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would be unable to do is 'save' results. Dr. Choudhary was consulted and felt that the trial version of the (b) (4) software would satisfy his needs. This was communicated to Dynavax. Dynavax shared that they had 3 licenses for the software and two of the licenses were in use and that they were unsure if a license could be 'transferred'.

Dynavax stated the version of the software being used is (b) (4)

CBER additionally had asked in Item #3 on the 9/2/16 IR that the 'concentration for' Anti-HBsAg Standards be reported in the COAs. Dynavax stated that these concentrations were listed in the cover letter of the July 28, 2016 submission and on the label of the actual materials. CBER requested that the COAs be updated to include the requested information as there were multiple labs testing and this information should be on the COAs. Dynavax agreed to do this and stated that they anticipate to respond to the 9/2/16 IR by the end of this week.

This concluded the call.