

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-DEC-2016 12:26 PM
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	CBER response to Dynavax emails of 11/22/16 requesting clarification of CRL items via an informal telecon
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body: After discussion with DVRPA leadership the following email was sent to Dynavax:

From: Berkhausen, Katherine
Sent: Thursday, December 01, 2016 12:26 PM
To: Alambra, Elaine

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Cc: Daemer, Richard J.

Subject: Response to clarification requests

Dear Elaine,

We acknowledge your communications with us regarding clarification of the CRL items (CRL issued on November 10, 2016). To avoid delays and inefficiencies, we request that you review the CRL comments in full and compile all your questions for clarification of the CRL and request a regulatory meeting. We refer you to the *Guidance for Industry: Formal Meetings between the FDA and Sponsor or Applicants*.

Kind regards,

Katherine

Katherine Berkousen
CAPT., US Public Health Service

FDA/CBER/Office of Vaccines
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