

RECORD OF EMAIL 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-AUG-2016 11:25 AM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	MCA - Meeting Communications - Additional
Related STNs	None
Related PMCs	None
Telecon Summary	Per CBER request and s/p telecom meeting, Dynavax has reviewed their HBV-16 revisions and confirms that no other datasets were affected
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Elaine Alambra [mailto:EAlambra@dynavax.com]

Sent: Thursday, August 04, 2016 11:25 AM

To: Berkhausen, Katherine

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Cc: Daemer, Richard J.

Subject: HEPLISAV BLA 125428 / 03aug2016 telecom re HBV-16 datasets

Dear Katherine,

As requested, the Dynavax participants at the 03 Aug 2016 telecom were:

Clinical

Robert Janssen, MD

William Heyward, MD

Kimberly Erby

Biostatistics

Robert Halstead

Brit Harvey

Biao Xing

Regulatory

Elaine Alambra

HBV-16 Datasets:

Also at this telecom, Dynavax was asked to identify any other datasets affected by changes to the HBV-16 ADSL datasets or confirm that no other HBV-16 datasets were affected. The ADSL issue we discussed at the telecom yesterday was regarding changes to per-protocol population variables values in HBV-16 that were made in ADSL.

Dynavax has reviewed HBV-16 and can confirm that no other datasets were affected.

Request:

Please provide a list of FDA participants at the 03 Aug telecom.

Thanks much,

Elaine

Elaine Alambra • Regulatory Affairs • Dynavax Technologies Corporation ☎ Tel: 510-665-0474 ✉ email: ealambra@dynavax.com