

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	05-AUG-2016 01:08 PM
Author	HULSE, ANDREA
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	CBER questions Dynavax's statement that no other datasets were affected by the erroneous dataset entries
FDA Participants	Katherine Berkousen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkousen, Katherine
Sent: Friday, August 05, 2016 1:08 PM
To: 'Elaine Alambra'
Cc: Daemer, Richard J.; Berkousen, Katherine
Subject: RE: HEPLISAV BLA 125428 / 03aug2016 telecom re HBV-16 datasets

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Dear Elaine,

Regarding our 8/3/16 telephone discussion of the inconsistencies in the HBV-16 datasets submitted to CBER and your email below:

Please provide your rationale for why the proposed changes to and the subsequent errors found in the revised ADSL HBV-016 datasets would not also impact the protd.xpt dataset, which contains the flags "NIPPFLG" and "LCPPFLG" in question?

Regards,
Katherine

From: Elaine Alambra [<mailto:EAlambra@dynavax.com>]
Sent: Thursday, August 04, 2016 11:25 AM
To: Berkhausen, Katherine
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:

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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