

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	16-AUG-2016 04:56 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	Immunogenicity data submitted for Study HBV-23 will not be reviewed- conveyed to Dynavax
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body:

Dynavax submitted immunogenicity data for study HBV-23 in their response to the Feb 2013 CR letter. Discussions were held with the clinical team, DVRPA management, as well as Carla Vincent and Chris Joneckis (Office of the Director/Associate Director for Review Management) and at the midpoint meeting with Dr. Gruber (Director, Office of Vaccines). Consensus was that immunogenicity data was not requested as part of the CR

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and the submission of immunogenicity data to support a claim in diabetes or other subpopulations, represents a new or modified indication under the review clock. This was conveyed to Dynavax in the email below.

From: Berkhausen, Katherine [<mailto:Katherine.Berkhausen@fda.hhs.gov>]

Sent: Tuesday, August 16, 2016 4:52 AM

To: Elaine Alambra

Cc: Berkhausen, Katherine; Daemer, Richard J.

Subject: Regarding HBV-23 Immunogenicity data

Dear Elaine,

This is to inform you that the immunogenicity data submitted in STN 125428/42 associated with Clinical Study HBV-023 will not be reviewed during this cycle. Additional immunogenicity data was not requested as part of the CBER Complete Response Letter issued on February 22, 2013.

We refer you to the document, *Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees* which states that "A request for approval of a new indication, or a modification of a previously approved indication, should be submitted individually in a separate supplement to an approved original application. The Agency does not recommend that new clinical or in vitro data, submitted in support of a new indication or claim, other than that required in safety updates be submitted as part of the pending supplement during the review of a given supplemental application. Such a submission would be considered developing the product on the review clock and is contrary to the spirit and intent of the Act."

We encourage you to request a pre-BLS meeting prior to any such submission.

Kind regards,

Katherine

Katherine Berkhausen
CAPT., US Public Health Service

FDA/CBER/Office of Vaccines
Div. of Vaccines & Related Products Applications
10903 New Hampshire Ave. WO71-3022
Silver Spring, MD 20993-0002