

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	15-DEC-2016 03:40 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	MCA - Meeting Communications - Additional AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Dynavax contacted to clarify and renumber the meeting questions which were not clearly outlined in the meeting/briefing packet.
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body:

Dynavax/Elaine Alambra was contacted to confirm the proposed meeting questions which were embedded in the various sections of the meeting/briefing packet. Each of the

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questions were discussed and renumbered for a total of 4 questions. When asked if the 4 questions were the only items that Dynavax was seeking clarification on, Elaine stated that Dynavax did have one more potential question that had not yet been communicated to CBER/DVRPA.

After internal discussion in DVRPA, I conveyed to Elaine that the submitted meeting request could be considered “incomplete” and we would allow Dynavax to add more questions but the 30 day clock would begin once a “complete” meeting packet was received. In a follow-up email, Dynavax opted to not add any more questions to the Type A meeting and that the meeting request received by CBER/DVRPA on December 14, 2016 was complete.

I confirmed that the objective of this Type A meeting was to clarify the specific CR letter items that Dynavax had identified and Elaine agreed that this was the intent of the meeting.

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

Sent: Thursday, December 15, 2016 4:50 PM

To: Berkhausen, Katherine

Cc: Daemer, Richard J.

Subject: Type A Meeting Request - HEPLISAV BLA 125428 / No additional questions

Hi Katherine,

Thank you for your call this afternoon. I am confirming that Dynavax does not intend to add any more questions to the Type A meeting request submitted on 13 Dec 2016.

We look forward to hearing back from the Agency.

Kind regards,

Elaine

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