

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	09-MAY-2017 11:52 AM
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's request to provide feedback on the proposed VRBPAC briefing presentation.
FDA Participants	Katherine Berkhausen; Dick Daemer; Sudhakar Agnihothram
Applicant Participants	Elaine Alambra

Telecon Body: Dynavax requested via a May 3, 2017 email, if CBER would discuss and provide feedback on the Dynavax presentation of the safety data and on cardiovascular events. This was discussed with DVRPA management (Branch and Division) and it was agreed that the applicant and CBER would independently present their findings at VRBPAC. As such, it would not be appropriate to provide input or feedback to Dynavax on their proposed presentation. Email communication is below.

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From: Berkhousen, Katherine
Sent: Tuesday, May 09, 2017 11:52 AM
To: 'Elaine Alambra'
Cc: Daemer, Richard J.; Agnihothram, Sudhakar
Subject: RE: HEPLISAV BLA 125428 / Dynavax VRBPAC presentation request

Dear Elaine,

We have discussed your May 3, 2017, request to provide feedback on the Dynavax VRBPAC presentation to ensure continuity with CBER's presentation. Given that both presentations are expected to be independent, it would not be appropriate for CBER to provide input on Dynavax's VRBPAC briefing or presentation. We therefore decline your request to align and discuss your presentation.

Kind regards,

Katherine

Katherine Berkhousen
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

Tel: (301) 796-1296
katherine.berkhousen@fda.hhs.gov

From: Elaine Alambra [<mailto:EAlambra@dynavax.com>]
Sent: Wednesday, May 03, 2017 9:32 PM
To: Berkhousen, Katherine
Cc: Daemer, Richard J.; Agnihothram, Sudhakar
Subject: HEPLISAV BLA 125428 / Dynavax VRBPAC presentation request

Dear Katherine,

To ensure alignment with CBER's presentation at VRBPAC, Dynavax is requesting the Agency's input and would welcome discussion on our proposed presentation of safety data and on cardiovascular adverse events (please see attached).

Given that the Briefing Book is due to the Agency on 27 June 2017, we would be grateful for a response within the next **3 weeks** to help us finalize our briefing materials and associated slide presentation.

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I will follow up with a phone call to you tomorrow, 4 May 2017 to confirm receipt of our VRBPAC proposal.

Thank you in advance for your consideration.

Kind regards,

Elaine

Elaine Alambra • Senior Director, Regulatory Affairs • Dynavax Technologies Corporation (Tel: 510-665-0474 * email: elambra@dynavax.com)