

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-SEP-2017 03:21 PM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Email to Dynavax requesting the Status Dynavax`s discussion with Kaiser Permanente
FDA Participants	Sudhakar Agnihothram, DVRPA
Applicant Participants	Elaine Alambra, Senior Director Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar

Sent: Friday, September 15, 2017 8:16 PM

RECORD OF TELEPHONE CONVERSATION

To: Elaine Alambra <EAlambra@dynavax.com>

Cc: Berkousen, Katherine <Katherine.Berkousen@fda.hhs.gov>; Daemer, Richard J. <Richard.Daemer@fda.hhs.gov>

Subject: RE: HEPLISAV BLA 125428: Proposed telecom re postmarketing study synopsis

Elaine,

Could you please let us know the status of Dynavax's discussion with Kaiser Permanente-Southern California to clarify the issues that were discussed during today's telecon?

Thanks,

Sudhakar

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

Sent: Friday, September 15, 2017 7:48 PM

To: Agnihothram, Sudhakar

Cc: Berkousen, Katherine; Daemer, Richard J.

Subject: RE: HEPLISAV BLA 125428: Proposed telecom re postmarketing study synopsis

Thank you!

Have a great weekend.

Elaine

RECORD OF TELEPHONE CONVERSATION

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

From: Agnihothram, Sudhakar [mailto:Sudhakar.Agnihothram@fda.hhs.gov]

Sent: Friday, September 15, 2017 4:47 PM

To: Elaine Alambra

Cc: Berkousen, Katherine; Daemer, Richard J.

Subject: RE: HEPLISAV BLA 125428: Proposed telecom re postmarketing study synopsis

Hi Elaine, I will let you know. Thanks, Sudhakar

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

Sent: Friday, September 15, 2017 6:35 PM

To: Agnihothram, Sudhakar

Cc: Berkousen, Katherine; Daemer, Richard J.

Subject: HEPLISAV BLA 125428: Proposed telecom re postmarketing study synopsis

Dear Sudhakar,

As a follow-up to our telecom this morning, Dynavax is requesting a telecom with FDA to (hopefully) finalize our discussions regarding the post marketing study synopsis.

Would the Agency be available for a telecom on Thursday, 21 Sept preferably between 9 to 11 AM Pacific Time? Alternatively, we can make ourselves available at a time that is convenient for the Agency.

RECORD OF TELEPHONE CONVERSATION

Please let me know.

With many thanks in advance,

Elaine

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

This email message is for the sole use of the intended recipient(s) and may contain confidential or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. The content of this message is subject to access, review and disclosure by the sender's email system administrator.

This email message is for the sole use of the intended recipient(s) and may contain confidential or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. The content of this message is subject to access, review and disclosure by the sender's email system administrator