

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	AGNIHOTHRAM, 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

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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.

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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

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