

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	19-JUL-2017 07:18 AM
Author	Silvia PerezVilar/Sudhakar Agnihothram
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	IR requesting details on expected annual accrual of hepatitis B vaccinees by vaccine group at Kaiser, as proposed by Dynavax.
FDA Participants	Sudhakar Agnihothram, Katherine Berkhausen and Richard Daemer
Applicant Participants	Elaine Alambra, Associate Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar

Sent: Wednesday, July 19, 2017 7:18 AM

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To: 'Elaine Alambra'

Cc: Berkousen, Katherine; Daemer, Richard J.

Subject: STN 125428 Information Request (IR) Regarding the Risk Management Plan

Dear Elaine,

Please find below our request for further information as detailed below.

Submissions Referenced in this IR:

Risk Management Plan Version 2.0. BLA 125428/ SEQ No. 0072

Response to Information Request 18 May 2017. BLA 125428/ SEQ No. 0088

Response to Information Request 7 June 2017. BLA 125428/ SEQ No. 0089

Your preliminary information indicates that you anticipate completing the recruitment of 40,000 Hepatitis B vaccine recipients within one year. Our feasibility estimates from Sentinel-PRISM suggest that your preliminary estimates may be too optimistic, and a realistic accrual may be a quarter to a third of that. Please confirm the expected annual accrual of hepatitis B vaccinees by Kaiser North and South per year, and provide more specifics about expected accrual by vaccine group (HEPLISAV vs. comparison vaccine).

Please provide the requested information by COB 7/25/17.

Please let us know if you have any questions.

Thanks,

Sudhakar

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