

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125428/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Dynavax Technologies Corporation / Lic. # 1883
<b>Product</b>	Hepatitis B Vaccine (Recombinant), Adjuvanted
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	19-JUL-2017 07:18 AM
<b>Author</b>	Silvia PerezVilar/Sudhakar Agnihothram
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	IR requesting details on expected annual accrual of hepatitis B vaccinees by vaccine group at Kaiser, as proposed by Dynavax.
<b>FDA Participants</b>	Sudhakar Agnihothram, Katherine Berkhausen and Richard Daemer
<b>Applicant Participants</b>	Elaine Alambra, Associate Director, Regulatory Affairs

### Telecon Body:

From: Agnihothram, Sudhakar

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

## **RECORD OF TELEPHONE CONVERSATION**

To: 'Elaine Alambra'

Cc: Berkhousen, 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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