

RECORD OF TELEPHONE CONVERSATION

Submission Information

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

Telecon Details

Telecon Date/Time	23-JUN-2017 07:35 AM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	IR requesting further information on the establishment of pregnancy registry.
FDA Participants	Sudhakar Agnihothram, Katherine Berkousen and Richard Daemer, RPMs DVRPA/OVR
Applicant Participants	Elaine Alambra, Senior Director Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar
Sent: Friday, June 23, 2017 7:33 AM
To: 'Elaine Alambra'

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Cc: Berkhausen, Katherine; Daemer, Richard J.

Subject: Information Request Re: STN 125428/0072

Dear Elaine,

Please find our request for the following information.

Reference to previous submission - **BLA 125428/0072**

We noted that in your Risk Management Plan version 2.0 you have proposed a Pregnancy Registry to monitor pregnancy outcomes in women exposed to HEPLISAV during pregnancy (section 1.16.1.2.2.2-Pregnant or lactating women).

Please submit a Concept Protocol for the proposed Pregnancy Registry as well as the projected dates and their justification for final protocol submission, study completion and final report submission by **COB 07/14/2017**

You may refer to the FDA Guidance for Establishing Pregnancy Registries at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071639.pdf

Please let us know if you have any questions.

Thanks,

Sudhakar

Sudhakar Agnihothram B.Pharm, Ph.D,

Primary Reviewer/ Regulatory Project Manager,

Division of Vaccine Related Product Applications,

Office of Vaccines Research and Review,

Center For Biologics Evaluation and Research,

10903, New Hampshire Avenue,

BLDG 71, 3215 C,

Silver Spring, Maryland, 20993.

Email: Sudhakar.Agnihothram@fda.hhs.gov

Ph: 301-348-3056