

# 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>	23-JUN-2017 07:35 AM
<b>Author</b>	AGNIHOTHARAM, SUDHAKAR
<b>EDR</b>	No
<b>Post to Web</b>	No
<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 further information on the establishment of pregnancy registry.
<b>FDA Participants</b>	Sudhakar Agnihothram, Katherine Berkousen and Richard Daemer, RPMs DVRPA/OVRR
<b>Applicant Participants</b>	Elaine Alambra, Senior Director Regulatory Affairs

### Telecon Body:

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

## RECORD OF TELEPHONE CONVERSATION

**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](http://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,

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