

# 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>	16-AUG-2017 03:49 PM
<b>Author</b>	AGNIHOTHAM, SUDHAKAR
<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>	An IR requesting the source of information (specific BLA sections) for the clinical data listed in Sections 6, 8 and 14 of the proposed label.
<b>FDA Participants</b>	Sudhakar Agnihothram, Richard Daemer and Katherine Berkousen
<b>Applicant Participants</b>	Elaine Alambra, Senior Director Regulatory Affairs

**Telecon Body:** **From:** Agnihothram, Sudhakar  
**Sent:** Wednesday, August 16, 2017 3:49 PM  
**To:** 'Elaine Alambra'  
**Cc:** Daemer, Richard J.; Berkousen, Katherine  
**Subject:** STN 125428/0 Request For Further Information

## **RECORD OF TELEPHONE CONVERSATION**

Dear Elaine,

Please provide the source of information (specific BLA sections) for the clinical data listed in Sections 6, 8 and 14 of the proposed label.

Thanks,

Sudhakar

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