

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	23-JUN-2017 04:09 PM
Author	AGNIHOTHRAM, SUDHAKAR
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Email clarification to submit the response to the IR sent on 06/23/17 by 07/07/17 instead of the originally requested date of 07/14/17.
FDA Participants	Sudhakar Agnihothram, Katherine Berkhausen, and Richard Daemer
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar [<mailto:Sudhakar.Agnihothram@fda.hhs.gov>]

Sent: Friday, June 23, 2017 1:07 PM

To: Elaine Alambra

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Cc: Berkhausen, Katherine; Daemer, Richard J.
Subject: RE: Information Request Re: STN 125428/0072

Hi Elaine,

I am writing with a clarification to the IR we sent this morning. Please submit your response to the IR by COB 07/07/17 instead of the originally requested date of 07/14/17. Please let us know if you have any questions.
Thanks, Sudhakar

From: Elaine Alambra [<mailto:EAlambra@dynavax.com>]
Sent: Friday, June 23, 2017 10:08 AM
To: Agnihothram, Sudhakar
Cc: Berkhausen, Katherine; Daemer, Richard J.
Subject: RE: Information Request Re: STN 125428/0072

Dear Sudhakar,

Acknowledged receipt.

Kind regards,

Elaine

Elaine Alambra • Senior Director, Regulatory Affairs • Dynavax Technologies Corporation ☎ Tel: 510-665-0474 ✉ email: ealambra@dynavax.com

From: Agnihothram, Sudhakar [<mailto:Sudhakar.Agnihothram@fda.hhs.gov>]
Sent: Friday, June 23, 2017 4:33 AM
To: Elaine Alambra
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**

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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,
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Division of Vaccine Related Product Applications,
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