

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	10-JUL-2017 07:37 PM
Author	Silvia Perezvilar
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	IR requesting more details on Pharmacovigilance Plan
FDA Participants	Sudhakar Agnihothram, Katherine Berkousen and Richard Daemer
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

Dear Elaine,
Please find our request for further information regarding the proposed Pharmacovigilance Plan.

Amendment Referred :

RECORD OF TELEPHONE CONVERSATION

Risk Management Plan Version 2.0. BLA 125428/ SEQ No. 0072

Response to Information Request 7 June 2017. BLA 125428/ SEQ No. 0089

You included in your reply to question 7 of the information request dated on 7 June 2017 a table (Table 1) with the anticipated events and power of at interim and final analyses of cardiac events to exclude a hazard ratio ranging from 2 to 5 under the assumption of background incidence rate ranging from 1/1000 to 5/1000 at different time points (1 year, 1.5 years, and 2 years).

Please provide further details on the statistical model and method used in the calculations, and as appropriate, all assumptions considered to make such calculations. If possible, please provide statistical software screenshots for each step in the calculation or coding scripts used.

Please also justify the appropriateness of the selected statistical model to investigate the risk of cardiac events following HEPLISAV administration. Which model you propose to use in the proposed post-marketing study to investigate (1) autoimmune diseases, (2) herpes zoster and, (3) if appropriate, other medically attended events?

Please provide a reply by COB **7/20/17**.

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