

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	29-SEP-2017 05:30 AM
Author	AGNIHOTHRAM, SUDHAKAR
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 detailing the Questions on Pregnancy Registry
FDA Participants	Marian Major, Katherine Berkhausen, Sudhakar Agnihothram and Richard Daemer
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

Dear Elaine,
Please find our request for further information on the Pregnancy Registry.

Reference to Amendment; STN#125428 Sequence 0091

RECORD OF TELEPHONE CONVERSATION

1. Please consider adding a group of pregnant women vaccinated with other hepatitis B vaccines as a primary comparison group. The method of assessment of the cases should be the same for both the exposed and comparator group.
2. You indicate that the primary outcomes of interest are major congenital malformations, preterm births, spontaneous abortions and stillbirths. Please consider adding maternal events, such as pre-eclampsia and thromboembolic events, as secondary outcomes.
3. Please clarify the criteria used for defining birth defects as “major”. Please use standardized case definitions for all the study outcomes.
4. Please provide sample size calculations based on the outcome with the smallest background rate and updated timelines based on these calculations.
5. Please confirm whether the protocol will include a third party to advise and participate in establishing and operating the registry, as well as assist in the review of data, classification of specific outcomes (when relevant), and the dissemination of information.
6. Please consider conducting periodic interim analyses of the data collected and providing results of those periodic analyses to the FDA.

Please provide your response by COB 10/06/2017.

Thanks,

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