

# 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>        | 29-SEP-2017 05:30 AM  |
| <b>Author</b>                   | AGNIHOTHRAM, 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>          | IR detailing the Questions on Pregnancy Registry                            |
| <b>FDA Participants</b>         | Marian Major, Katherine Berkhausen, Sudhakar Agnihothram and Richard Daemer |
| <b>Applicant Participants</b>   | 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

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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,

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