

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	08-JUNE-2017 03:00PM
Author	AGNIHOTHARAM, SUDHAKAR
EDR	No
Post to Web	Yes
Outside Phone Number	18777464263
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	To update Dynavax on the clinical safety Issues that CBER plans to discuss at the upcoming VRBPAC meeting scheduled to be on July 28, 2017.
FDA Participants	Sudhakar Agnihothram, Richard Daemer, Marian Major, Wellington Sun, and Philip Krause
Applicant Participants	Rob Janssen, Graeme Currie, and Elaine Alambra

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Telecon Body:

On 06/08/17, a teleconference between CBER and Dynavax was held. The purpose of the teleconference was to provide Dynavax with an update on the Clinical Safety Issues that CBER plans to discuss at the upcoming VRBPAC meeting scheduled to be held on July 28, 2017.

CBER indicated that they continue to have concerns regarding the imbalance in the Acute Myocardial Infarction (AMI) observed in the Heplisav group compared to the group that received Engerix in the studies DV HBV-23, 16 and 10. CBER pointed out that they will be discussing this issue at the VRBPAC meetings scheduled on July 28, 2017. Furthermore, CBER suggested that an indication for use of HEPLISAV-B in the limited age group (e.g., in individuals 18-59 years of age) might mitigate the concerns regarding the AMI, and analysis of the clinical data to support such an indication is being considered by CBER, and may be considered by VRBPAC as well. Dynavax questioned whether CBER had arrived at any conclusions from such an analysis, and CBER responded that no final conclusions have been drawn yet. CBER asked Dynavax if they had considered presenting on these items at VRBPAC, and Dynavax responded that they had looked at some of these factors in specific subgroups but that the outcome with respect to cardiac events did not change. Dynavax asked if FDA would like to see any of this data and CBER responded that we were not asking for additional data at this time and that if anything were to be sent we would not be reviewing it before VRBPAC. CBER indicated that this may be data they would want to see following VRBPAC.

Dynavax further indicated that they are committed to evaluate risks due to the AMI, and are in the process of enrolling subjects for the Post Marketing Study. Dynavax anticipates having 20,000 individuals in each Heplisav and Engerix group and they plan to provide Heplisav-B at (b) (4) to Kaiser Permanente in Southern California. Dynavax further indicated that they are working on submitting a revised pharmacovigilance plan, by the week of June 12, 2017. CBER concluded the teleconference by reemphasizing that they will be discussing the cardiac safety issues at the VRBPAC.