

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.0
Review Office	OVR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	01-AUG-2017 03:00-03:330 PM
Author	AGNIHOTHAM, 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	To inform Dynavax that the Pharmacovigilance Proposal submitted in the BLA is inadequate, and re-emphasize VRBPAC's recommendation to submit an adequate pharmacovigilance plan.
FDA Participants	Sudhakar Agnihothram, Richard Daemer, Marian Major, Wellington Sun, and Marion Gruber.
Applicant Participants	Rob Janssen, Graeme Currie, Randy Hyer , and Elaine Alambra

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Telecon Body: CBER indicated that the reason for this call was to provide Dynavax with an update after the VRBPAC discussions on the Heplisav-B BLA. Below are the key points discussed during the telecon.

- CBER emphasized the VRBPAC recommendation that the current Pharmacovigilance Plan (PVP) is inadequate.
- CBER acknowledged that the current Action Due Date (ADD) for this BLA was August 10, 2017 but that the development of a new PVP would not be possible by this date.
- CBER indicated that they will be issuing an Information Request in the near future requesting Dynavax to submit a high-level draft of a revised Pharmacovigilance Plan, which should address the concerns raised by the VRBPAC.
- This synopsis of the pharmacovigilance plan needs to be submitted on or before the action due date of August 10, 2017.
- This submission would be considered as a Major Amendment, resulting in a 3 month extension to the ADD..
- The new ADD for the BLA will be Nov 9, 2017.
- This will provide Dynavax with sufficient time to develop a detailed PVP to fully address the VRBPAC concerns.
- CBER indicated that they will be open for focused meetings to discuss the necessary elements of the revised Pharmacovigilance Plan once the Major Amendment has been issued.
- CBER further noted that a full detailed PVP plan is not required for the November 9, 2017 regulatory action on the Heplisav-B BLA, but CBER needs to agree with the Pharmacovigilance Plan.
- CBER informed Dynavax that they should submit the revised PVP by the end of September to allow sufficient time for CBER to review and proceed with further negotiations if necessary.
- Dynavax asked if there were any other regulatory pathways to address this issue but CBER informed them that a Major Amendment was the most appropriate course.
- Finally, Dynavax indicated that they will work with CBER to provide all the necessary information to arrive at a regulatory decision. They requested whether CBER can arrive at a regulatory decision prior to the ACIP (American Council of Immunization Practices) meeting on October 25, 2017.
- CBER responded that their review will depend on the data submitted by Dynavax, and they will be in communication with Dynavax if they need any further information.
- CBER summarized that the August 10, 2017 ADD would not occur but that an Information Request would be issued the response to which would constitute a Major Amendment. CBER would then be willing to set up a telecom to discuss the revised PVP with Dynavax. Dynavax would provide a full, detailed synopsis of the revised PVP by the end of September.