



Memorandum

DATE June 15, 2017

FROM Bhanu Kannan, Bioresearch Monitoring Branch
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THROUGH Carrie Mampilly, M.P.H., Director, Division of Inspections and Surveillance

TO Marian Major, Ph.D., Chair, BLA Licensing Committee
Richard Daemer, Ph.D., RPM
Katherine Berkhausen, RPM
Sudhakar Agnihothram, Ph.D., RPM

SUBJECT Bioresearch Monitoring Discipline Review Memo -Third Review Cycle
APPLICANT: Dynavax Technologies Corporation
Biologics Licensing Application (BLA): STN 125428/0
PRODUCT: HEPLISAV™ (HBsAg-1018)

Final summary statement:

The Bioresearch Monitoring (BIMO) review of the sponsor response to information requested in a letter dated November 10, 2016 did not reveal substantive problems impacting the submitted study data.

BIMO review:

BIMO reviewed the sponsor response dated February 8, 2017 to items #41 and #42 in the complete response (CR) letter sent to the sponsor on November 10, 2016. The sponsor's response to CR item #42, use of an excel table with inadequate access control to capture protocol deviations, did not reveal significant issues. However, BIMO requested clarification from the sponsor in an information request (IR) dated April 6, 2017 for the response to CR item #41, discrepant data in subjects lost to follow-up and reengaged between the sponsor submitted data and data collected during the BIMO inspection. The sponsor responded on May 1, 2017 to FDA's IR sent on April 6, 2017. BIMO's review finds the response to be acceptable.

Should you have any questions or comments about the contents of this memo or any aspect of BIMO, please contact me at 240-402-8979.

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Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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