



Our STN: BL 125428/0

**MAJOR AMENDMENT ACKNOWLEDGEMENT**

Dynavax Technologies Corporation  
Attention: Elaine Alambra  
2929 Seventh Street, Suite 100  
Berkeley, CA 94710

Dear Ms. Alambra:

We received your August 8, 2017, amendment to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Hepatitis B Vaccine (Recombinant), Adjuvanted, on August 9, 2017.

We consider your submission a major amendment because your submission contains

- a substantial amount of new data not previously submitted to or reviewed by the Agency

and will add an additional three months to the time by which we should complete our review. Therefore, the action due date is November 9, 2017.

If you have any questions, please contact the Regulatory Project Managers Katherine Berkousen, Richard Daemer, or Sudhakar Agnihothram at 301-796-2640.

Sincerely yours,

Wellington Sun, M.D.  
Director  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research