



MAJOR AMENDMENT ACKNOWLEDGEMENT

Our STN: BL **125428/0**

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

Dear Ms Alambra:

We received your April 8, 2016, amendment to your Biologics License Application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for Hepatitis B Vaccine (Recombinant), Adjuvanted on April 11, 2016.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the *Food and Drug Administration Safety and Innovation Act* of 2012 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 December 15, 2016.

If you have any questions, please contact the Regulatory Project Manager, CAPT Katherine Berkhouse, at 301-796-2640.

Sincerely yours,

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