



RESUBMISSION ACKNOWLEDGEMENT

Our STN: BL 125428/0

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

Dear Ms. Alambra:

We have received your February 7, 2017, resubmission to your supplement to your biologics license application for Hepatitis B Vaccine (Recombinant), Adjuvanted on February 8, 2017.

The resubmission contains additional clinical information that you submitted in response to our November 10, 2016, complete response letter.

We consider this a complete, class 2 response to our action letter. Therefore, the user fee goal date is August 10, 2017.

If you have any questions, please contact Dr. Richard Daemer or Captain Katherine Berkhausen at (301) 796-2640.

Sincerely yours,

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