



Our STN: BL **125428/0**

Dynavax Technologies Corporation
Attention: William Turner
2929 7th Street, Suite 100
Berkeley, CA 94710

Dear Mr. Turner:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated April 26, 2012, for Hepatitis B Vaccine (Recombinant), to determine its acceptability for filing. Under 21 CFR 601.2(a), we have filed your application today. The review goal date is February 24, 2013. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We will contact you regarding your proposed labeling no later than January 24, 2013. If post marketing study commitments (506B) are required, we will contact you no later than January 24, 2013.

At this time, we have not identified any potential review issues for inclusion in this letter. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Managers, Richard Daemer, Ph.D. and Ms. Katherine Berkhausen, Regulatory Project Managers, at (301) 796-2640.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
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