



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20852-1448

Our STN: BL **125428/0**

Dynavax Technologies Corporation  
Attention: William Turner  
2929 7<sup>th</sup> 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  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research