



Our STN: BL **125428/0**

Dynavax Technologies Corporation
Attention: Mr. William Turner
2929 Seventh Street, Suite 100
Berkeley, CA 94710

Dear Mr. Turner:

We have reviewed your submission dated October 26, 2012 to your biologics license application (BLA) for your Hepatitis B Vaccine (Recombinant), Adjuvanted, requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed name, HEPLISAV, is not acceptable. The basis for our decision is:

Your proposed name is considered false or misleading within the meaning of 21 U.S.C. 352(a) and 321(n).

There is no hepatitis strain designation in the proposed name. This misleadingly implies that HEPLISAV is effective against multiple strains of hepatitis when, in fact, HEPLISAV is only indicated for the prevention of hepatitis B infection.

You may submit a new proprietary name for FDA consideration. Any alternate proprietary name(s) should comply with the regulations regarding false, misleading or fanciful names and should not be confused with other medicinal products with orthographic or phonological similarities.

If you have any questions, please contact Dr. Richard Daemer or Captain Katherine Berkhausen 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