SUPPLEMENT APPROVAL

OUR STN: BL 125428/1

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

March 22, 2018

Dear Ms. Alambra:

We have approved your request dated November 17, 2017, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Hepatitis B Vaccine (Recombinant), Adjuvanted (HEPLISAV-B) to include a pre-filled syringe (PFS) presentation, to be manufactured at (b) (4) facility. Under this approval, we are approving the following:

- A new manufacturing facility (b) (4) for drug product manufacturing, filling, labeling and packaging of the PFS presentation

- Manufacturing changes applicable to the PFS presentation:
  - Increased (b) (4)
  - Removal of the (b) (4)
  - Streamlined formulation process for improved manufacturing efficiency and control

LABELING
We hereby approve the draft package insert labeling,the draft container and carton labels submitted on November 17, 2017.

Please provide your final content of labeling including the carton and container labels in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to BLA STN 125428 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely yours,

Jerry Weir, PhD.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research