

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.0
Review Office	OVRR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	04-JAN-2013 12:50 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	OT -
Related STNs	None
Related PMCs	None
Telecon Summary	After the 2012 VRBPAC meeting, Dynavax emails and proposes to change their indication to adults who are or who may be at risk of HBV infections or are in settings where HBV is recommended.
FDA Participants	K. Berkhausen; R. Daemer
Applicant Participants	W. Turner; T. Martin

Telecon Body: Following the 2012 VRBPAC discussions, Dynavax is proposing to modify their indication to adults at risk or potentially at risk for HBV infection or for individuals in settings where HBV vaccine is recommended. Below is the email from Bill Turner.

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From: Turner, William [<mailto:wturner@dynavax.com>]
Sent: Friday, January 04, 2013 12:50 PM
To: Daemer, Richard J.; Berkousen, Katherine
Cc: Martin, Tyler
Subject: HEPLISAV - indication proposal

Dear Dick and Katherine,

Dynavax has reviewed the video and the transcript from the VRBPAC meeting following our meeting with CBER on 19 DEC 2012. Based on that review and our discussions with you at the meeting, we believe that the following changes to the indication take into consideration the committee perspective that HEPLISAV has clear immunogenicity and regimen/adherence advantages that would be of benefit to individuals at high risk of infection and addresses the concern raised by a few of the members that the size of the database (~4500) might not be adequate to support a general indication for persons 18-70 years of age. As the ACIP has identified persons at increased risk of infection, and US adult HBV vaccination policy is to immunize at-risk persons, not the general population, this modified indication would provide further guidance and clarification to what persons would be most likely to benefit from HEPLISAV.

The proposal is to use the general risk categories in the indication, and identify the specific categories (with reference to the ACIP recommendations) elsewhere in the PI.

The proposed indication is:

HEPLISAV is indicated for immunization against infection caused by all known subtypes of Hepatitis B Virus (HBV) in adults 18 through 70 years of age, who are or may be at risk of HBV infection, or are in settings where HBV vaccination is recommended:

- ***Persons at risk for infection by sexual exposure***
- ***Persons at risk for infection by percutaneous or mucosal exposure to blood***
- ***International travelers to regions of endemic HBV infection***
- ***Settings in which hepatitis B vaccination is recommended for all adults***

As stated above, in support of this indication, we also propose the following detailed description to be included in the labeling:

Adults recommended to receive hepatitis B vaccination include the following:

Persons at risk for infection by sexual exposure

- ***Sex partners of hepatitis B surface antigen (HBsAg)-positive persons***

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- *Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)*
- *Persons seeking evaluation or treatment for a sexually transmitted disease*
- *Men who have sex with men*

Persons at risk for infection by percutaneous or mucosal exposure to blood

- *Current or recent injection-drug users*
- *Household contacts of HBsAg-positive persons*
- *Residents and staff of facilities for developmentally disabled persons*
- *Health-care and public safety workers with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids*
- *Person with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients*
- *unvaccinated persons with diabetes mellitus.*

Others

- *International travelers to regions with high or intermediate levels (HBsAg prevalence of $\geq 2\%$) of endemic HBV infection*
- *Persons with chronic liver disease*
- *All other persons seeking protection from HBV infection*

Settings in which hepatitis B vaccination is recommended for all adults:

- *Sexually transmitted disease treatment facilities*
- *Human immunodeficiency virus testing and treatment facilities*
- *Facilities providing drug-abuse treatment and prevention services*
- *Health-care settings targeting service to injection-drug users*
- *Correctional facilities*
- *Health-care settings targeting services to men who have sex with men*
- *Institutions and nonresidential day care facilities for developmentally disabled persons*

I understand that the review team will need to consider this proposal - Tyler and I are available at any time to discuss this further. Please call me at (510) 717-0833 (mobile) if you have any questions or comments. If this approach is acceptable to CBER, I will need guidance on how to officially file to the BLA.

Best regards,
Bill

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