

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	20-MAR-2017 12:41 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	CBER guidance/advice to 3.17.17 email questions
FDA Participants	Katherine Berkhausen
Applicant Participants	Elaine Alambra

Telecon Body: Dynavax emailed me with an update on the lot release for Lot #1033385. Additionally, three questions were posed to CBER. The CBER response is embedded in the email in bold font.

From: Elaine Alambra [mailto:EAlambra@dynavax.com]

Sent: Friday, March 17, 2017 10:54 AM

To: Berkhausen, Katherine

Cc: Daemer, Richard J.

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Subject: HEPLISAV BLA Resubmission / Upcoming Submissions

Happy St Patrick's Day, Katherine –

This is a follow-up to my phone call this morning. I wanted to give you a heads up on what's coming your way today, 17 March 2017.

Lot Release for Lot 1033385 (update)

- The Product Release Branch (PRB, Cheryl Hulme) contacted me on 08 Mar2017 requesting that we update the LRP for Lot 1033385 to add the sterility method and the maximum valid dilution for the ^{(b) (4)} test. This LRP was previously submitted during the review of the first CRL responses. A courtesy copy will be emailed to you today.
- Related to the above, we took the opportunity to update the Lot Release Template to align with the changes requested. This updated Lot Release Template will be submitted formally to the BLA and also provided to PRB. A redlined version will accompany the submission to show the changes made.
- In addition, to reflect the recent personnel changes at Dynavax, an updated Lot Release Contact Information will be provided to PRB.
- o Should this also be filed formally to the BLA – or would a courtesy copy be sufficient? Please let me know.

Other items I'd like to follow up on are:

1. The Agency previously indicated that external consultation on the MI (myocardial imbalance) information would be requested. Based on this consultation, is there anything Dynavax can clarify and / or expand on? We would like to respond to this and any other clinical questions as soon as we can.

CBER Response: The submission is under active review by the clinical team. We appreciate Dynavax's willingness to provide any additional clarification. We will contact Dynavax should we have any questions.

2. As you can imagine, we are anxious to know whether the Agency has decided to take HEPLISAV to VRBPAC and if / when can that information be shared with Dynavax?

CBER Response: Whether or not to go to VRBPAC is currently under internal discussion. CBER should be able to provide an answer to this question by the 1st week of April.

3. Also, does the Agency intend to conduct additional inspections – GCP and/or GMP – during this review cycle?

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CBER Response: At this point in time, I am not aware of any plans to conduct additional GCP or GMP inspections. Should this change we would of course, notify Dynavax.

We would be very grateful for your input as it would be extremely helpful in Dynavax's planning and preparation.

Thank you in advance – and kind regards,

Elaine

Elaine Alambra • Regulatory Affairs • Dynavax Technologies Corporation ☐ Tel: 510-665-0474 ☐ email: ealambra@dynavax.com