

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	16-OCT-2013 12:36 PM
Author	DAEMER, RICHARD
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Response to Dynavax's 10/9/13 question if adding an immunogenicity subset would still qualify for Class 2 resubmission when responding to the CR letter.
FDA Participants	Daemer, Richard; Berkhausen, Katherine
Applicant Participants	William Turner; Elaine Alambra

Executive Summary: Dynavax emailed CBER on Oct 9, 2013, with a question “*Can you confirm that if we added an immunogenicity subset (such as Diabetics) to this study that it would still be considered a Class 2 resubmission with the response to the CRL?*” This question was discussed with the reviewers and with management and it was decided that the Dynavax CR response would still be considered a Class 2 resubmission and reviewed under the 6 month clock.

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Communication Exchanges between CBER and Dynavax:

From: Daemer, Richard J. [<mailto:Richard.Daemer@fda.hhs.gov>]
Sent: Wednesday, October 16, 2013 12:36 PM
To: Turner, William; Alambra, Elaine
Cc: Berkhausen, Katherine; Major, Marian
Subject: RE: Class 2 resubmission (CRL response) clarification

Dear Bill,

Anything submitted in the CRL response will be considered as a Class 2 resubmission and will be reviewed under a 6 month clock.

Regards,

Dick

From: Turner, William [<mailto:wturner@dynavax.com>]
Sent: Wednesday, October 16, 2013 2:38 PM
To: Daemer, Richard J.; Alambra, Elaine
Cc: Berkhausen, Katherine
Subject: RE: Class 2 resubmission (CRL response) clarification

Dear Dick and Katherine,
Eddie Gray has asked that I check in again to see if we might be able to get any direction *today* on this question regarding whether including an immunogenicity subset would alter the Class 2 resubmission review timeline (6 months). I sincerely appreciate that you are doing your best with this however, he expects to be addressing the investor community tomorrow morning.

Regards,
Bill

From: Turner, William
Sent: Tuesday, October 15, 2013 10:34 AM
To: 'Daemer, Richard J.'; Alambra, Elaine
Cc: Berkhausen, Katherine
Subject: RE: Class 2 resubmission (CRL response) clarification

Thanks Dick. I'm sure everyone is swamped over there. We expect to announce our money raising efforts for the trial shortly and anticipate this question might come up. Anything you can do would be extremely helpful.

Regards,
Bill

From: Daemer, Richard J. [<mailto:Richard.Daemer@fda.hhs.gov>]
Sent: Tuesday, October 15, 2013 9:39 AM
To: Turner, William; Alambra, Elaine
Cc: Berkhausen, Katherine
Subject: RE: Class 2 resubmission (CRL response) clarification

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Bill,

We are waiting for feedback from our clinicians and management. Please be aware that they have other issues and files they are dealing with.

From: Turner, William [<mailto:wturner@dynavax.com>]
Sent: Tuesday, October 15, 2013 11:24 AM
To: Berkhausen, Katherine; Daemer, Richard J.
Cc: Alambra, Elaine
Subject: RE: Class 2 resubmission (CRL response) clarification

Dear Katherine,

In follow-up to my voicemail from this morning, have you been able to confirm as to whether the inclusion of an immunogenicity subset would still be considered a Class 2 resubmission with the response to the CRL? As far as I can tell from the guidance documents it would be – it seems to me the only other alternative is a withdrawal and re-submission of the BLA. That does not seem appropriate to me but obviously I'm not quite clear on this. Thank you for your help.

Regards,
Bill

*William Turner
Acting Vice President
Regulatory Affairs*

*Dynavax Technologies
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Suite 100
Berkeley, CA 94710*

510-665-7296

From: Berkhausen, Katherine [<mailto:Katherine.Berkhausen@fda.hhs.gov>]
Sent: Thursday, October 10, 2013 7:18 AM
To: Turner, William; Daemer, Richard J.
Cc: Alambra, Elaine
Subject: RE: Class 2 resubmission (CRL response) clarification

Dear Bill and Elaine,

Just acknowledging receipt of your email. I will discuss this with our team and provide feedback as soon as I have it. Regarding Elaine's email yesterday, know that we are actively working to provide feedback to you regarding you Aug 30th email/questions to us. I hope to have something soon as I know you are patiently waiting to hear from us.

Katherine

RECORD OF TELEPHONE CONVERSATION

From: Turner, William [<mailto:wturner@dynavax.com>]
Sent: Wednesday, October 09, 2013 6:26 PM
To: Daemer, Richard J.; Berkhausen, Katherine
Cc: Alambra, Elaine
Subject: Class 2 resubmission (CRL response) clarification

Dear Dick and Katherine,

I know we haven't proposed this as part of the current discussion and review around the upcoming Dynavax study, but we are considering adding an immunogenicity co-primary objective to this study. At the 05 June 2013 meeting*, FDA stated that the data from this study would be a part of the CRL response and a Class 2 resubmission (6 month review). Can you confirm that if we added an immunogenicity subset (such as Diabetics) to this study that it would still be considered a Class 2 resubmission with the response to the CRL?

Best regards,
Bill

*William Turner
Acting Vice President
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***CBER COMMENT:** It is noted that the official meeting minutes from the Type C face to face meeting held on June 5, 2013 do not reference any agreements regarding immunogenicity data or review of such data. Dr Gruber stated in her opening comments at this meeting that the immunogenicity of Heplisav has been demonstrated and CBER had concerns of the product's overall 'safety'.