

(System Info - 229149 BERKHOUSEN KATHERINE 02/28/2013 15:57:31
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RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125428/0 Office: OVRR

Product: Hepatitis B Vaccine (Recombinant), Adjuvanted

Applicant: Dynavax Technologies Corporation

Telecon Date/Time: 28-Feb-2013 03:15 PM Initiated by FDA? Yes

Telephone Number:

Communication Categoric(s): Advice

Author: KATHERINE BERKHOUSEN

Telecon Summary:

Response to Dynavax email requesting information on setting up meeting with CBER

FDA Participants: Katherine Berkhausen

Non-FDA Participants: Bill Turner and Elaine Alambra

Telecon Body:

Dynavax requested feedback on how best to move forward with responding to the CR letter and setting up a meeting (see email below). I contacted Bill Turner and stated that depending on the extent of the Dynavax questions/concerns that CBER would be happy to hold a telecon to 'clarify' any of the CR letter comments. If Dynavax was seeking a more in-depth discussion, it would be best for them to request a Type C meeting. Bill Turner stated that Dynavax was already preparing a formal meeting request, that they would be requesting a Type A meeting, and would provided background information as well as specific questions related to the over 40 age group as well as the chronic kidney disease group as a possible path to licensure. Bill additionally stated that they also had a few concerns regarding some of the CMC related comments and would also state that in their letter. He did say that Dynavax would be open to separating the clinical and the CMC issues; and that the CMC issues could possibly be discussed in a separate telecon. Bill stated that Dynavax is looking to hold this regulatory meeting with CBER in early to mid April.

This concluded the call.

*Tue 2/26/2013 7:16 PM
Dear Dick and Katherine,*

This is not the official notification but I was hoping for some guidance around requesting a meeting regarding the CRL. Within 10 days of the CRL we will officially notify you of our intent to file an amendment. In addition, we will be requesting a meeting to discuss the steps necessary for approval. As we will have questions regarding both the CMC review and the Clinical review would it be possible for us to request two separate meetings? I know this is possible during the clinical development phase but I wasn't sure if that was appropriate for a discussion around items in a CRL.

*Regards,
Bill*

*William Turner
Vice President
Regulatory Affairs and
Corporate Quality Systems*