

(System Info - 231231 BERKHOUSEN KATHERINE 03/22/2013 12:17:46
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RECORD OF TELEPHONE CONVERSATION

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

Product: Hepatitis B Vaccine (Recombinant), Adjuvanted

Applicant: Dynavax Technologies Corporation

Telecon Date/Time: 14-Mar-2013 05:15 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies): Meeting Communications - Additional

Author: KATHERINE BERKHOUSEN

Telecon Summary: Type A meeting denial with discussion of alternate path forward (type C meeting)

FDA Participants: Loris McVittie, Marian Major, Rakesh Pandey, Richard Daemer, and Katherine Berkousen

Non-FDA Participants: Bill Turner, Elaine Alambra, Steven Tuch, Edi Smith

Telecon Body:

Dynavax submitted a Type A meeting request dated March 11, 2013, proposing specific questions. Dynavax proposed questions were grouped as relating to clinical, CMC, and administrative. CBER initiated this phone call to Dynavax.

Regarding the clinical questions: In response to the six clinical questions (BLA 125428/0/33) CBER responded that a Type A meeting is premature. This type of meeting is generally reserved for sponsors that have tried to address CR issues and have failed. We do not agree that Dynavax is at this point. However CBER recognizes that as Dynavax works on addressing the CR issues, discussion is warranted on their proposals to address clinical indication and safety concerns. A Type C meeting is the appropriate mechanism for such discussions. In order for a meaningful discussion to occur, CBER stated that Dynavax's must submit a complete meeting package with supporting arguments for each of their indication-related proposals, including how they view them in preference order and the timelines by which they think they can be accomplished. CBER stated that a telecon to discuss the meeting material could be scheduled approximately 30 days from our receipt of an adequate and complete meeting package. CBER told Dynavax that we really need to focus on getting the preapproval indication/safety issues resolved so that any discussion of their proposed postapproval Kaiser study would be very limited; they were fine with that since they are still working on protocols with Kaiser. Dynavax concurred with CBER's comments.

Regarding the CMC questions: CBER proposed to discuss the CMC/Manufacturing questions with Dynavax in a separate telephone call from the clinical issues. The CBER response could involve written comments at which point Dynavax could request an informal t-con to discuss clarification if necessary.

Regarding the administrative question: Not addressed in any detail on this call.