

(System Info - 223054 BERKHOUSEN KATHERINE 01/02/2013 14:34:32
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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: 27-Nov-2012 01:20 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Advice

Author: KATHERINE BERKHOUSEN

Telecon Summary:
Advice on how to proceed in requesting a meeting with FDA s/p VRBPAC.

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

CBER contacted Dynavax in response to Dynavax's request for a meeting. M. Major clarified that we would like a list of specific questions to focus the meeting. The proposed questions would assist CBER with understanding Dynavax's concerns and would ensure that the appropriate CBER people would be at the meeting.

T. Martin expressed concern regarding the VRBPAC outcome and the committee members concern regarding safety of their product. He stated that the Dynavax team felt that the 'Dynavax briefing document' and the 'CBER briefing document' were very similar in content and data that was presented; yet, the VRBPAC committee members focused on safety concerns that were not presented in the briefing documents. M. Major encouraged Dynavax to pose this concern as a question to be discussed at the meeting.

She additionally stated that there may be a need to have additional meetings to help Dynavax with a path forward.

Dynavax asked if the clinical team has concerns that were not brought up in the CBER presentation or the briefing document. M. Major responded that this would be an appropriate question to ask at the proposed meeting.

B. Turner stated that he wanted to ensure that the clinical team is aware of Dynavax's commitment to working closely with CBER as has been done the last 7 years during their vaccine product's development. He stated that Dynavax feels that despite the fact that Study 10 was conducted off-IND, which Dynavax did seek CBER guidance and involvement; Dynavax felt that this point was not correctly reflected during the VRBPAC discussions. M. Major stated that it was ok to discuss these things but suggested that Dynavax might want to focus on the path forward.

B. Turner stressed that Dynavax was working to respond and address any of the outstanding information requests. He also stated that they have been in contact with D. Sullivan regarding the 483 response. B. Turner additionally stated that Dynavax would propose meeting questions and email them to D. Daemer. B. Turner stated that Dynavax's intention is to request that a meeting be held within the next couple of weeks. T. Martin suggested a face-to-face meeting as a means to collaborate more closely as he felt that sometimes communication is misunderstood in a phone conference. M. Major stated that a face-to-face meeting is not necessarily better and perhaps an audio-visual meeting might meet everyone's needs just as well.

This concluded the call.