

(System Info - 210040 BERKHOUSEN KATHERINE 08/16/2012 14:35:25
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RECORD OF TELEPHONE CONVERSATION

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

Product:
Hepatitis B Vaccine (Recombinant)

Applicant:
Dynavax Technologies Corporation

Telecon Date/Time: 16-Aug-2012 01:00 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Other - VRBPAC Notification

Author: KATHERINE BERKHOUSEN

Telecon Summary:
The sponsor was notified that this product will be going to VRBPAC for discussion

FDA Participants: Katherine Berkhausen; Marion Major; Christine Walsh

Non-FDA Participants: William Turner; Elaine Alambra; Tyler Martin

Trans-BLA Group: No

Related STNs: None
Related PMCs: None

Telecon Body:

The sponsor was contacted and notified that this product is being discussed at VRBPAC on November 14, 2012. Don Jehn is the CBER VRBPAC Coordinator and will be the Dynavax POC for briefing documents, presentation and timelines. William Turner identified himself as the Dynavax POC for VRBPAC. Dynavax was told that the agenda for that day is still being developed but more than likely discussions about their product would take the majority of the day. We would continue to work closely with Dynavax.

Dynavax had no additional questions or comments and this concluded the call.