

(System Info - 217790 BERKHOUSEN KATHERINE 11/05/2012 09:33:54
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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: 05-Nov-2012 08:30 AM Initiated by FDA? Yes

Communication Category: Information Request

Author: KATHERINE BERKHOUSEN

Telecon Summary:

Request to provide the treatment arm for each of the subjects noted in the case report forms.

FDA Participants: K. Berkhausen

Non-FDA Participants: E. Alambra

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Email to sponsor requesting that Dynavax provide additional information related to the case report forms (CRF) that were submitted to the BLA. CBER requests that Dynavax provide the treatment arm information; whether subjects received Heplisav or Engerix-B. This information can be provided via a listing or a table with the subject's ID information and which vaccine was received.