

(System Info - 223478 BERKHOUSEN KATHERINE 01/07/2013 13:49:38
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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: 13-Nov-2012 12:00 PM Initiated by FDA? Yes

Communication Category(ies): Advice

Author: KATHERINE BERKHOUSEN

Telecon Summary:

Dynavax notified that CBER would be discussing an identified adverse event of Tolusa Hunt at VRBPAC.

FDA Participants: K. Berkousen, R. Daemer, L. Smith, and L. Schrager

Non-FDA Participants: William Turner and Tyler Martin

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

We contacted the sponsor to give them a 'heads-up' that CBER reviewers would be presenting in the clinical presentation at VRBPAC, information on a specific adverse event that was identified during the clinical review of the BLA, namely the case of Tolusa Hunt. The telecon is a courtesy call to inform the Dynavax team.

Dynavax thanked us for the call and had no further comments.