

(System Info - 221326 DAEMER RICHARD 12/12/2012 13:53:29 DAEMER)

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: 06-Nov-2012 05:05 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:
IR regarding which labs performed Ab assays

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Please provide information regarding which laboratories performed the antibody assays in studies 10 and 16.