

(System Info - 221318 DAEMER RICHARD 12/12/2012 13:34:15 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 03:00 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:
CRFs w/AE (renal)

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Please provide the case report forms for the subjects reporting the following adverse events as outlined in Table 9.2.5 of the ISS: acute renal failure, renal failure, and renal impairment. Please provide a courtesy copy via email as soon as possible, optimally by COB today or first thing tomorrow morning.