

(System Info - 213581 BERKHOUSEN KATHERINE 09/20/2012 12:59:09
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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: 10-Aug-2012 03:23 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: RICHARD DAEMER

Telecon Summary: IR #6 Request for BIMO information

FDA Participants: Richard Daemer

Non-FDA Participants: Elaine Alambra, William Turner

Telecon Body:

Since study sites 22, 23, 24, 25, and 26 have disbanded and the investigator has left the institution, please indicate where CBER can find these records.

Dr Reisinger is still responsible for the data generated from his sites. You have not indicated that another investigator has taken over the study. We have previously requested during the pre-BLA meeting if the investigator has left the institution to identify the replacement.