

(System Info - 207748 BERKHOUSEN KATHERINE 08/01/2012 14:56:33
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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: 01-Aug-2012 02:19 PM Initiated by FDA? Yes

Telephone Number: 510-665-0474

Communication Categoric(s): Information Request

Author: KATHERINE BERKHOUSEN

Telecon Summary:

Request for correction to FDA Form 356h Establishment Information

FDA Participants: Katherine Berkousen and Richard Daemer

Non-FDA Participants: Elaine Alambra

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Requested information regarding the FDA Form 356h Establishment Information. On page 4/7, the table titled ***Hepatitis B Surface Antigen (HBsAg) Drug Substance***, contains information related to 'drug product' manufacture and not drug substance. We requested a corrected copy of the 356h which Dynavax agreed to send in to the submission.