

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: 26-Jul-2012 02:45 PM Initiated by FDA? Yes

Telephone Number: via secure email to William Turner at wturner@dynavax.com

Communication Category(ies): Information Request

Author: KATHERINE BERKHOUSEN

Telecon Summary:

Requesting SOP for in-vivo potency assay and clarification of (b) (4).

FDA Participants: Katherine Berkhausen

Non-FDA Participants: William Turner

Related STNs: None

Related PMCs: None

Telecon Body:

Sponsor contacted via email to request the following information:

Section 3.2.P.5.2 (Analytical Procedures)

*Please provide the SOP for Heplisav: In-Vivo Potency Assay, Part II: Immunization of (b) (4) and Harvesting of Sera.

Section 4.2.1 (Pharmacology)

*On page 3 of Study 99-0086, please clarify whether the HBsAg used for (b) (4) is the same as the one for immunization of the (b) (4) or not. If not, please provide the source for the HBsAg used to (b) (4)