

(System Info - 221298 DAEMER RICHARD 12/12/2012 12:29:43 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: 05-Oct-2012 01:40 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:
Clinical safety and product

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Please provide the following information:

1. Please clarify exactly which lot or lots were used in study DV2-HBV-10.
2. Please either submit a dataset containing the safety lab data collected at baseline and all follow-up timepoints during study DV2-HBV-16, or direct the reviewer to the location of this dataset within the submission.
3. Please provide the validation studies that support the (b) (4) limits for the (b) (4)

(b) (4)

4. Please provide the results of the Hold Time Validation studies performed on the

(b) (4)