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: 07-Nov-2012 07:35 PM   Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:
IR regarding which labs used to generate immunogenicity data in

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
Clarification regarding which laboratory generated the study HBV-10 immunogenicity data

In your data-mgmt-plan.pdf (Section 5.3.5.1.3 -HBV-10, page 10 of 51), you state:

Laboratory Results
Central Lab Collection
1 (b) (4) lab will be used for this protocol.
2. The central lab will send a cumulative lab transfer on a predetermined basis to Data Management.
3. DM programmers will extract central lab data from data transfer and datasets will be created.
4. The serology samples had to be retested at (b) (4) (instead of (b) (4)) using the (b) (4) assay not
the   (b) (4)   per the protocol due to an assay recall. These data were converted into SAS datasets
but were not loaded into the database.

Please clarify: Data from which lab were included in the "final" database for Study DV2-HBV-10?
                    (b) (4)   ?