

(System Info - 227789 BERKHOUSEN KATHERINE 02/13/2013 16:40:43
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RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125428/0 Office: OVR

Product: Hepatitis B Vaccine (Recombinant), Adjuvanted

Applicant: Dynavax Technologies Corporation

Telecon Date/Time: 13-Feb-2013 03:30 PM Initiated by FDA? Yes

Telephone Number: 510-665-0474

Communication Category(ies): Information Request

Author: KATHERINE BERKHOUSEN

Telecon Summary:

Request for imaging studies referenced in Jan 31, 2013 submission but not submitted to the BLA due to technical difficulty

FDA Participants: Katherine Berkousen and Dick Daemer

Non-FDA Participants: voice mail of Elaine Alambra

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Dr. Daemer and I contacted Dynavax to clarify the status of the imaging studies that were requested in the December 19, 2012 meeting with Dynavax. A voice mail was left for Ms. Alambra requesting an update and to additionally request that Dynavax ensure that the imaging studies are viewable and are not in violation of HIPPA.

The January 31, 2013 amendment to the BLA references that Dynavax is having difficulty submitting these files via the electronic gateway due to file extensions and that Dynavax was working with FDA IT staff to resolve the problem. Dynavax did submit imaging studies in the form of a 'courtesy copy' to the clinical reviewer via FedEx: but, the disk containing the images obtained during the subject's hospitalization failed to open. Additionally, the two disks that are viewable contain personal identifiable information on each image which must be removed before being submitted to the file. The 'courtesy copy' was to be followed with an official submission to the BLA. To date, the requested information has not been submitted to the BLA. Dynavax is requested to submit the imaging studies to the BLA in a viewable format once the above issues have been addressed.