

(System Info - 229651 BERKHOUSEN KATHERINE 03/05/2013 14:28:30
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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: 28-Feb-2013 12:30 PM Initiated by FDA? Yes

Communication Category(ies): Advice

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Telecon Summary:

Discussion on submitting radiological images

FDA Participants: K. Berkhausen, R. Daemer, G. Heavner, L. Smith, J. Montgomery, R. Pandey

Non-FDA Participants: Bob Burke (IT), Tanya Cope (Clinical), Robert Janssen (Clinical), Edie Smith (Project Mgmt), William Turner, and Elaine Alambra (Regulatory)

Telecon Body:

CBER requested this call with Dynavax to follow-up on the issue of a site license for the software viewer. The images that Dynavax intends to submit require viewing software. CBER asked the Dynavax team what kind of file format the radiological images were in. Dynavax stated that their images were in a DICOM (*.dcm) format. J. Montgomery thought that this type format is an industry standard and that it might be possible that CBER has the capability to view these types of images. There are many viewing software programs and it is possible that FDA already has a license for DICOM viewing software. J. Montgomery will follow-up with this. CBER requested that Dynavax remove all personal information from one of the images and send the *.dcm image to K. Berkhausen in an email as a test image. If the CBER team can view the test image, we will ask our consultants if they are able to view *.dcm files. J. Montgomery will collaborate with FDA IT personnel to find viewing software for the DICOM formatted files. Dynavax reiterated that if necessary they are willing to provide a software site license if needed. The CBER team felt that this was not necessary at this time and that we would prefer to locate a DICOM viewing software program within FDA first. If the CBER team is unable to procure DICOM viewing software, then we would ask Dynavax for a site license.