

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: 27-Feb-2013 02:00 PM Initiated by FDA? Yes

Communication Category(s): Advice

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Telecon Summary: Guidance provided regarding submitting imaging studies to the BLA

FDA Participants: K. Berkhausen, R. Daemer, M. Major, G. Heavner, L. Smith, D. Schwab

Non-FDA (Dynavax) Participants: B. Burke, T. Cope, R. Janssen, E. Smith, W. Turner, E. Alambra

Telecon Body:

This telecon was requested by Dynavax in response to the CBER Complete Response letter dated February 22, 2013, specifically to better understand CBER's request for the radiological images as denoted in Comment #3. Dynavax requested specific guidance related to comment # 3 a – c and 3 e. Dynavax indicated that it was complicated to provide information to us in the formats requested. They noted that there was previous communication between M. Gruber and T. Martin.

Regarding Comment 3a, removal of patient identifiers from the images: Dynavax requested clarification on what exactly was meant by patient identifiers. Would this include age, sex and medical record number? The disks containing the imaging studies came from two different hospitals which resulted in two different imaging formats. FDA clarified that name, age, sex, medical record numbers were all considered personal patient identifiers. Only the subject study ID number should be on the image. Additionally the date of the imaging study should be denoted in some manner. Dynavax asked if this scrubbing of personal information was due to HIPPA. FDA explained that it is to comply with 21 CFR 20.63(b) as denoted in the CR letter. Dynavax stated that the two hospitals had done all they can, but Dynavax would remove the personal information.

Regarding Comment 3b, separating the software from images: Dynavax stated that the images are currently embedded in the disk along with the viewing software. CBER

reiterated as stated in the CR letter, that the software must be submitted separately from the images on a separate disk along with an appropriate site license. This is an issue with respect to processing and storing of electronic media.

Regarding Comment 3c., the site license: Dynavax requested clarification on what is required for a site license and if CBER would require a single license holder or multiple license holders and for what length of time. CBER stated they would follow-up on this.

Regarding Comment 3e, submitting multiple disks: Dynavax asked if CBER is requesting 5 copies of the disks because this information is being sent to consultants. CBER replied that yes, the images and software disks would be sent to both our clinical reviewers and our consultants.

In conclusion, Dynavax agreed to: remove the personal data from the images; separate the viewing software from the images and provide each on a separate disk; provide 5 copies of each disk; and provide the software licenses as requested.

CBER requested that Dynavax keep us informed of their progress and the estimated time of submitting this information to us. Additionally, CBER will provide Dynavax with the length of time required for a site license. G. Heavner offered to be a point of contact for Dynavax for this issue and will provide them with her phone number.