

(System Info - 234268 BERKHOUSEN KATHERINE 04/24/2013 11:35:11  
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### **RECORD OF EMAIL COMMUNICATION**

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

Product: Hepatitis B Vaccine (Recombinant), Adjuvanted

Applicant: Dynavax Technologies Corporation

Telecon Date/Time: 24-Apr-2013 10:05 AM Initiated by FDA? Yes

Communication Category(ies): Information Request

Author: KATHERINE BERKHOUSEN

Telecon Summary: IR # 24 Request for info related to CRL item #2

FDA Participants: K. Berkhausen, R. Daemer, M. Major

Non-FDA Participants: W. Turner, E. Alambra

Telecon Body:

We have the following information request related to Dynavax's response to item #2 of the CRL dated February 22, 2013 and Dynavax's response submitted in their meeting request dated April 10, 2013 (125428/0/34). The following request was made to Dynavax in an email.

- 1) A link to a rheumatology consult was provided for subject 21-640, however just an email exchange and a brief rheumatology follow-up note are provided within that link. Please provide the original rheumatology evaluation.
- 2) Subject 22-070 had a positive anticardiolipin antibody and elevated Factor VIII activity noted during his hypercoagulability workup. It was recommended that these labs be repeated within 6 weeks. Dynavax states they had a conversation with the patient and he reports that no cause for his clot/PE (and subsequent clot on ACL repair) was found, but there is no specific notation/discussion regarding the results of the repeat labs, specifically the anticardiolipin antibody. Please provide this information.