

(System Info - 221645 DAEMER RICHARD 12/14/2012 13:25:25 DAEMER)

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: 21-Nov-2012 05:07 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:
IR #23 Source documents for subject 40-616

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
Dear Bill and Elaine,

- 1. Please provide all source documents for subject 40-616 from study DV2-HBV-16.*
- 2. As per the discussion between Dr. Tyler Martin and Dr. Marion Gruber on November 16, 2012, please provide the expert consultation report(s) you obtained regarding the potential diagnosis of Tolosa-Hunt syndrome for subject 40-616.*

You may send a courtesy copy via email as soon as possible with subsequent submission through the gateway.

In addition, as a follow-up to VRBPAC you indicated that you would contact us to discuss a possible path forward. Please request a meeting in writing and provide a briefing document with the specific items you may wish to discuss and any comments you may have.