

(System Info - 221307 DAEMER RICHARD 12/12/2012 13:11:43 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: 01-Nov-2012 10:54 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):  
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:  
Clinical Safety CRF's

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

1. Please submit the case report forms en bloc for the subjects in which the following adverse events listed in Table ISS 9.2.5 beginning on page 993 occurred: Basedow's disease, Goiter, Hyperparathyroidism, Hyperthyroidism, Hypothyroidism, Thyroid Disorder, Thyroid Mass, Thyroiditis, Uveitis, Diabetes Mellitus, Blood thyroid stimulating hormone decreased, and Thyroxine decreased.

2. Page 125 of the Clinical Summary of Safety states that ISS Listing 3.1 contains a link to the complete narrative for each subject experiencing an SAE. This table does not contain any links. Please provide these narratives en bloc at this time.

Please respond by COB today. You can send by email and then as an official submission. nter details of telecon here]