

(System Info - 214381 DAEMER RICHARD 09/27/2012 13:49:29 DAEMER)

## RECORD OF TELEPHONE CONVERSATION

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

Product:  
Hepatitis B Vaccine (Recombinant)

Applicant:  
Dynavax Technologies Corporation

Telecon Date/Time: 24-Sep-2012 12:00 AM Initiated by FDA? Yes

Telephone Number: 510-665-6474

Communication Categorie(s):  
1. Other -

Author: RICHARD DAEMER

Telecon Conversation with Dynavax about several issues and Information Requests.

FDA Participants: Katherine Berkousen, Richard Daemer

Non-FDA Participants: Elaine Alambra

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

We spoke with Elaine Alambra about the following:

1. Information Request #5: Establishment issues: We asked when the sponsor would respond to this request. Elaine said Dynavax was hoping to respond the week of 9/24/12 or the following week.
2. We requested that Dynavax create a table listing when they received CBER's various IR's, the date of their response . They should note if they are providing responses to the entire IR and if not which items they are responding to.
3. Status of labeling revisions for removal of superiority claims as stipulated by CBER during telecon with CBER on 7/11/12 Elaine believed Nov would

suffice. We requested that Dynavax send the revised draft labeling as soon as it is available.

4. We requested that Elaine cc us on emails/comments related to lot release to keep us informed
5. Elaine confirmed that they planned to respond to the Establishment 483 by November 20, 2012.
6. Elaine confirmed that IR #9 for clinical safety data would be sent the week of 9/24/12 or the following week.