

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

|                         |  |
|-------------------------|--|
| <b>Application Type</b> | BLA  |
| <b>STN</b>              | 125428/0.0                                     |
| <b>Review Office</b>    | OVRR   |
| <b>Applicant</b>        | Dynavax Technologies Corporation / Lic. # 1883 |
| <b>Product</b>          | Hepatitis B Vaccine (Recombinant), Adjuvanted  |
| <b>Trans-BLA Group:</b> | No   |

## Telecon Details

|                                 |   |
|---------------------------------|---|
| <b>Telecon Date/Time</b>        | 07-APR-2016 04:31 PM  |
| <b>Author</b>                   | BERKHOUSEN, KATHERINE   |
| <b>EDR</b>                      | No  |
| <b>Post to Web</b>              | Yes   |
| <b>Outside Phone Number</b>     |   |
| <b>FDA Originated?</b>          | Yes   |
| <b>Communication Categories</b> | IR - Information Request  |
| <b>Related STNs</b>             | None  |
| <b>Related PMCs</b>             | None  |
| <b>Telecon Summary</b>          | IR for location of the Dynavax revised datasets for HBV-10 and HBV-16 |
| <b>FDA Participants</b>         | Katherine Berkhausen  |
| <b>Applicant Participants</b>   | Elaine Alambra  |

**Telecon Body:** Request for the location within the submission of the revised datasets to Study 10 and Study 16

**From:** Berkhausen, Katherine

**Sent:** Thursday, April 07, 2016 4:31 PM

**To:** Alambra, Elaine

**Subject:** 125254/0/42 clarification request

## RECORD OF TELEPHONE CONVERSATION

Dear Elaine,

Please identify the location of the revised datasets for HBV-10 and HBV-16 in your submission 125428/0/42 submitted on March 16, 2016.

Kind regards,

*Katherine*

Katherine Berkousen  
CAPT., US Public Health Service

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