

RECORD OF TELEPHONE CONVERSATION

Submission Information

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

Telecon Details

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

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

From: Berkousen, Katherine

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

To: Alambra, Elaine

Subject: 125254/0/42 clarification request

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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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