

# 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>	03-MAR-2017 02:27 PM
<b>Author</b>	BERKHOUSEN, KATHERINE
<b>EDR</b>	No
<b>Post to Web</b>	No
<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>	Request (b) (4) Endotoxin (b) (4) Test Method SOP
<b>FDA Participants</b>	Katherine Berkhausen
<b>Applicant Participants</b>	Elaine Alambra

### Telecon Body:

From: Berkhausen, Katherine  
Sent: Friday, March 03, 2017 2:27 PM  
To: Alambra, Elaine  
Cc: Daemer, Richard J.  
Subject: IR-2

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Dear Elaine,

CBER requests a copy of your (b) (4) Endotoxin (b) (4) Test Method SOP (SOP QBA 060) on or before 10 March, 2017.

Kind regards,

Katherine

Katherine Berkousen  
CAPT., US Public Health Service  
FDA/CBER/Office of Vaccines  
Div. of Vaccines & Related Products Applications  
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