

# 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>	22-MAR-2017 01:41 PM
<b>Author</b>	KONG, HYESUK
<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>	Follow up request for endotoxin (b) (4) test method SOP also for the dilution of test sample SOPs
<b>FDA Participants</b>	Katherine Berkhausen; Richard Daemer
<b>Applicant Participants</b>	Elaine Alambra

### Telecon Body:

From: Berkhausen, Katherine  
Sent: Wednesday, March 22, 2017 1:41 PM  
To: Alambra, Elaine  
Cc: Daemer, Richard J.; Berkhausen, Katherine

## RECORD OF TELEPHONE CONVERSATION

Subject: IR for 125428/0

Dear Elaine,

We have the following Information Request

CBER originally requested a copy of your (b) (4) endotoxin (b) (4) test method SOP (QBA060) in an information request dated March 3, 2017. However, Dynavax provided two other SOPs (RL-SOP-00860 and SOP DYN-QC-004) in their response(submission dated March 13, 2017). Please confirm if these SOPs number are correct or clarify how these are related to the SOP QBA060. In addition, CBER requests the SOP (QBA073) used for performing dilutions of test sample.

Kind regards,

Katherine  
Katherine Berkhousen  
CAPT., US Public Health Service  
FDA/CBER/Office of Vaccines  
Div. of Vaccines & Related Products Applications  
10903 New Hampshire Ave. WO71-3022  
Silver Spring, MD 20993-0002  
Tel: (301) 796-1296  
katherine.berkhousen@fda.hhs.gov