

RECORD OF TELEPHONE CONVERSATION

Submission Information

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	03-MAR-2017 02:27 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Request (b) (4) Endotoxin (b) (4) Test Method SOP
FDA Participants	Katherine Berkhausen
Applicant Participants	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 Berkhausen
CAPT., US Public Health Service
FDA/CBER/Office of Vaccines
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