

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	14-OCT-2016 11:59 AM
Author	CAMPBELL, KAREN
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	
FDA Participants	Katherine Berkhousen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkhousen, Katherine
Sent: Friday, October 14, 2016 12:41 PM
To: Alambra, Elaine <EAlambra@dynavax.com>
Cc: Daemer, Richard J. <Richard.Daemer@fda.hhs.gov>
Subject: IR regarding lot release protocol

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Dear Elaine,

- 1) In the lot release protocol template submitted on 9/28/2016, in amendment 125428/.64, we note that the incorrect address is being used for the sample custodian. Please change this to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Sample Custodian
10903 New Hampshire Avenue
WO75-

G707

Silver Spring, MD 20993-0002

- 2) Please submit an updated protocol to the BLA by October 25, 2016. Once this correction is made you may submit the lot release protocol to the sample custodian for the launch lot that was submitted.

Kind regards,

Katherine

Katherine Berkousen
CAPT., US Public Health Service

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