

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	26-JUL-2016 01:08 PM
Author	CAMPBELL, KAREN
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	IR to revise and resubmit LRP template
FDA Participants	Katherine Berkhousen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkhousen, Katherine

Sent: Tuesday, July 26, 2016 12:52 PM

To: Alambra, Elaine

Cc: Berkhousen, Katherine

Subject: IR 125428 Lot Release request

Dear Elaine,

RECORD OF TELEPHONE CONVERSATION

We continue to review your submission for STN 125428 and have the following IR regarding the Lot Release Protocol Template which was submitted in STN 125428/0.42 on 16-Mar-2016. Please revise and resubmit your LRP template within 3 weeks of receiving this request.

1. The header on each page must include:

Cc: 125428 /1883/FC

page x of y

Lot Number:

Other information is not needed in the header and it should be listed below this information if it is included.

2. On pages 2, 4 and 6 of 6, please remove 'Sterile' from the sterility test specification. The specification should be 'no growth'.

3. On page 2 of 6, Purified Antigen, please add (b) (4) tests.

4. On page 4 of 6, please update the specification for HBsAg (b) (4).

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue with our review.

Kind regards,

Katherine

Katherine Berkhausen
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