

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,

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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

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