

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-AUG-2016 12:00 PM
Author	CHOUDHARY, ANIL
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	IR for specific documents related to reagents, software, and standards; some of which came in has hardcopy with the shipment of samples/reagents but should be in the electronic database
FDA Participants	Katherine Berkousen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Elaine Alambra [mailto:EAlambra@dynavax.com]

Sent: Wednesday, August 03, 2016 12:00 PM

To: Berkousen, Katherine

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Subject: RE: HEPLISAV BLA 125428 shipment of reagents and standards / IR dated 24 May 2016

Hi Katherine,

Acknowledged receipt.

Kind regards,

Elaine

Elaine Alambra • Regulatory Affairs • Dynavax Technologies Corporation (Tel: 510-665-0474 * email: ealambra@dynavax.com)

From: Berkhausen, Katherine [<mailto:Katherine.Berkhausen@fda.hhs.gov>]

Sent: Wednesday, August 03, 2016 8:59 AM

To: Elaine Alambra

Subject: RE: HEPLISAV BLA 125428 shipment of reagents and standards / IR dated 24 May 2016

Dear Elaine,

Please submit the following documents to the official file.

- Preparation protocol DUS-PP-0384-02 (Vaccine (b) (4)).
- Preparation protocol PP228-03 1 x (b) (4) (original and translated version)
- DUS-SOP-QC-0089-09 In vivo Potency Assay Part III: Measurement of titers + 3 appendices
- DUS-SOP-QC-0204-01 (b) (4) software + 2 appendices

Thank you.

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