

RECORD OF EMAIL/TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.42
Review Office	OVRR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	29-MAR-2016 08:35 AM
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	IR1 For manufacturing schedule and POC
FDA Participants	Katherine Berkhusen
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkhusen, Katherine
Sent: Tuesday, March 29, 2016 8:35 AM
To: Alambra, Elaine
Cc: Daemer, Richard J.
Subject: IR 125428/0/42
Importance: High

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Dear Elaine,

We have the following requests regarding your submission 125428/0/42. Please provide the:

- Manufacturing schedule for the months of May and June 2016 of the drug substance manufacturing facility (Rhein Biotech GmbH (a wholly owned subsidiary of Dynavax Technologies Corporation located at Eichsfelder Strasse 11 40595 Düsseldorf Germany); and
- Contact person from Dynavax, who DMPQ can contact for the preparation of this re-inspection.

We request that you provide this information by close of business on April 1, 2016.

Kind regards,

Katherine

Katherine Berkhausen
CAPT., US Public Health Service

FDA/CBER/Office of Vaccines
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