

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	30-MAR-2017 07:03 PM
Author	AGNIHOTHRAM, SUDHAKAR
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	OT -
Related STNs	None
Related PMCs	None
Telecon Summary	This document contains questions regarding testing related to the Heplisav Product Shipping. These questions were sent in advance to Dynavax to enable them to prepare for a telecon on 4/3/2017.
FDA Participants	Berkhousen; Daemer; Agnihothram
Applicant Participants	Elaine Alambra

Telecon Body:

From: Berkhousen, Katherine
Sent: Thursday, March 30, 2017 11:38 AM
To: Alambra, Elaine <EAlambra@dynavax.com>

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Cc: Berkhausen, Katherine <Katherine.Berkhausen@fda.hhs.gov>; Daemer, Richard J. <Richard.Daemer@fda.hhs.gov>; Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>

Subject: Questions for the Telecon scheduled Monday April 3, 2017

Dear Elaine,

Below find the questions to be discussed in our telecon with Dynavax on Monday April 3, 2017 at 11:00.

1. Regarding page 4 of 63 from the Summary Report PD-2012-09, in which the results of the OQ study were documented in the Distribution Simulation Final Report, (b) (4) in support for the response to the CR item #45.a.
 - a. You stated that this OQ study was a simulation of the (b) (4) at a temperature between 2°C to 8°C. However, it is unclear if the (b) (4) testing conducted at a temperature between 2°C to 8°C are representative of the (b) (4) of the vials during (b) (4) shipment conditions. Please clarify if the (b) (4) testing at a temperature between 2°C to 8°C conducted in this OQ study simulate the (b) (4) of the vials and duration during (b) (4) shipment conditions.
 - b. You did not state if any testing has been conducted to the unlabeled drug product vials to determine if there are changes in the product quality at the end of the OQ study. Please corroborate if any product quality testing has been conducted to these vial at the end of the OQ study. If so, please indicate the testing conducted to these vials and results.
2. Regarding assessment PD-2016-04, which describe the comparison of the results and conclusions from PD-2012-09 with the expected routine shipping of the unlabeled vials from Rentschler to (b) (4) in support for the response to the CR item #45.b.
 - a. It is unclear if you compared the (b) (4) transportation methods of the unlabeled vials from Rentschler to the labeling and packaging locations located in (b) (4). Please clarify if you conducted a comparison of the (b) (4) transportation methods of the unlabeled vials from Rentschler to these labeling and packaging locations. If so, please provide a summary of this comparison and an assessment of the impact the differences have on the product. If not, please provide a rationale to not conduct this comparison.

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- b. You did not specify in this assessment if there is any change in the shipping configuration, target shipping temperatures and acceptance criteria evaluated in PD-2012-09, since the shipping of HEPLISAV unlabeled vials from Rentschler to (b) (4) are through (b) (4) transportation. Please clarify if there is any change in the shipping configuration, target shipping temperatures and acceptance criteria evaluated in PD-2012-09, since the shipping of HEPLISAV unlabeled vials from Rentschler to (b) (4) are through (b) (4) transportation.
- c. You stated in page 3 of this assessment that the expected shipping time from Rentschler to (b) (4) is less than (b) (4). However, it is unclear how you determined this shipping time since it appears that no shipment was sent to (b) (4) yet. Please clarify if you sent any shipment of unlabeled HEPLISAV Drug Product Rentschler to (b) (4) to corroborate that the expected shipping duration is less than (b) (4). Alternative, please justify how you determined the shipping time to be less than (b) (4).
- d. Please corroborate if identity testing has been and will be conducted to the labeled drug product vials according to 21 CFR 610.14 and where this testing is conducted.

Kind regards,
Katherine Berkhausen

Katherine

Katherine Berkhausen
CAPT., US Public Health Service

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