

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	27-OCT-2017 09:31 AM
Author	AGNIHOTHAM, SUDHAKAR
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	IR to Dynavax requesting details on Identity testing of the final labeled drug product.
FDA Participants	Sudhakar Agnihothram, Marian Major , Sara Gagnetten
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar

Sent: Friday, October 27, 2017 9:31 AM

To: Elaine Alambra <EAlambra@dynavax.com>

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

Subject: **STN 125428/0 Information Request on Identity Testing of Final labeled Drug Product**

Dear Elaine,

Below, please find our request for further information on the identity testing of the final labeled drug product, as required by 21 CFR 610.14.

As discussed during the telecon on October 26, 2017 the Code of Federal Regulations (21 CFR 610.14) require that the contents of a final container of each filling of each lot shall be tested for identity after all labeling operations shall have been completed. Currently Dynavax does not perform an identity test on the contents of the final labeled product produced at (b) (4) facilities. Please add an identity test to the Drug Product specifications in Section 3.2.P.5.1 of the BLA.

This can be done by renaming Table 3.2.P.5.1-1 as “Heplisav-B Final Container Specifications” and adding a second table, Table 3.2.P.5.1-2 titled “Final Product (Labeled and Packaged) Release Specification” with the chosen identity test and the acceptance criterion. Please submit this revised section to the BLA.

Please confirm that Dynavax commits to performing this test at Dynavax, Dusseldorf on representative samples from all final labeled lots generated at (b) (4) for distribution in the U.S.

Please let us know if you have any questions.

Thanks,

Sudhakar

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