

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125428/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Dynavax Technologies Corporation / Lic. # 1883
<b>Product</b>	Hepatitis B Vaccine (Recombinant), Adjuvanted
<b>Trans-BLA Group:</b>	No

## Telecon Details

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