

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	26-OCT-2017 01:00 PM
Author	AGNIHOTHRAM, 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	Summary of Telecon to discuss the requirement of the Identity testing of the Final Labeled Drug Product
FDA Participants	Sudhakar Agnihothram, Richard Daemer, Iryna Zubkova

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Applicant Participants	Elaine Alambra Mike Berry Martin Gohlke David Novack Catherine Pedersen Maureen Urban
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Telecon Body:

Dynavax was asked if there is an identity test in place for final labeled product produced by (b) (4). Dynavax responded that an identity test is performed on naked vials filled at Rentschler. At the time of filling, the aluminum crimping on the neck of the vial is stamped with the lot number and the vials are sent to (b) (4). The stamp on the neck of the vials is checked against the printed label once labeling is completed at (b) (4). (b) (4) also performs a (b) (4) test for 1018 ISS adjuvant on each lot that they receive from Dynavax.

CBER informed Dynavax that the stamping on the vial crimping did not fulfill the Code of Federal Regulations requiring that the contents of a final container of each filling of each lot shall be tested for identity after all labeling operations have been completed. Dynavax proposed that (b) (4) perform an additional (b) (4) test for the 1018 ISS adjuvant following vial labeling. CBER explained that this would not constitute an identity test and that if (b) (4) were to perform the test it would have to be validated at the (b) (4) facility before approval.

Dynavax agreed to arrange for the return to Germany of labeled vials from (b) (4) for final release testing using one of the approved identity tests, either for HBsAg or 1018 ISS adjuvant, and apply the same release criterion as that applied during final container testing at the Rentschler Dynavax QC lab.

Dynavax agreed to add this as a test to the Drug Product specifications, Section 3.2.P.5, 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 Release Specification" with the identity test and the acceptance criterion. This revised section will be submitted to the BLA.