

# 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>	21-SEP-2017 11:42 AM
<b>Author</b>	AGNIHOTHARAM, 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 requesting details on In-Process Testing, Information on the UNII CODE, and Date of Manufacture of the Final Drug Product
<b>FDA Participants</b>	Sudhakar Agnihothram, DVRPA
<b>Applicant Participants</b>	Elaine Alambra, Senior Director, Regulatory Affairs

### Telecon Body:

**From:** Agnihothram, Sudhakar

**Sent:** Thursday, September 21, 2017 11:03 AM

**To:** Elaine Alambra <EAlambra@dynavax.com>

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

## RECORD OF TELEPHONE CONVERSATION

<Richard.Daemer@fda.hhs.gov>

**Subject:** HEPLISAV BLA 125428 / Laboratory sites for In-Process Tests, UNII Code.

Hi Elaine,

Below please find our response regarding your request for the in-process testing, Information on the UNII code and our request for information regarding the date of manufacture for the final drug product.

1. The information regarding in-process tests performed by different labs, referenced in your email below, should be submitted as a CBE-0 *post licensure*. Please include any validation reports from the testing labs for these tests, the full addresses for the testing labs and FEI numbers.
2. Please clarify how you define the date of manufacture for your final vaccine product relative to the production stage (e.g. final sterile filtration, final fill, date of final formulation). If this information is located in the BLA please indicate the section.
3. UNII code for the CPG 1018 adjuvant is H0E71D85ZS and the description will be DNA, D(P-THIO)(T-G-A-C-T-G-T-G-A-A-C-G-T-T-C-G-A-G-A-T-G-A), sodium salt.

Please let us know if you have any questions.

Thanks,

Sudhakar