

# 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>	08-MAY-2017 04:37 PM
<b>Author</b>	Garnepudi, Varsha
<b>EDR</b>	No
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	AD - Advice
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Clarification of the CBER IR dated May 4, 2017 of EU/ml vs IU/ml
<b>FDA Participants</b>	Katherine Berkousen; R. Daemer; S. Agnihothram
<b>Applicant Participants</b>	Elaine Alambra

**Telecon Body:** CBER provides clarification of the May 4, 2017 IR requesting Dynavax to use the WHO International Endotoxin Standard (IU) as it is the standard available via NIBSC. This change should be incorporated in all of the Lot Release Protocol pages.

**From:** Berkousen, Katherine

**Sent:** Monday, May 08, 2017 4:37 PM

**To:** 'Elaine Alambra'

## RECORD OF TELEPHONE CONVERSATION

**Cc:** Daemer, Richard J.; Agnihothram, Sudhakar

**Subject:** RE: Information Request - STN 125428/0.77 Dynavax Hepatitis B Vaccine (Recombinant), adjuvanted

Dear Elaine,

As a follow-up to your email below and recent voice mail seeking clarification regarding the request to change EU/ml to IU/ml in the Lot Release Protocol, please note the information below:

1. CBER no longer provides an Endotoxin Standard (EU), thus only the WHO International Endotoxin Standard (IU) is available via NIBSC. This is the reason for the change, which we are requesting of all manufacturers.
2. Please incorporate this request throughout the *entire* document (i.e. page 2 and 3 of LRP template change EU/mg to IU/mg also page 4 and 5 change EU/mL to IU/mL).

Kind regards,  
Katherine