

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

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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