

RECORD OF TELEPHONE CONVERSATION

Submission Information

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

Telecon Details

Telecon Date/Time	04-MAY-2017 07:14 AM
Author	Varsha Garnepudi
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	An email IR from DBSQC requesting changes in the Lot Release Template
FDA Participants	Sudhakar Agnihothram, Orchards Daemer, and Katherine Berkousen, RPMS, OVRP/DVRPA
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar
Sent: Thursday, May 04, 2017 7:14 AM
To: 'Elaine Alambra'
Cc: Berkousen, Katherine; Daemer, Richard J.

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

Good Morning Elaine.

We are reviewing your submission for STN 125428 and have the following request for information regarding the Lot Release Protocol Template submitted in 125428/0.77 on 17-Mar-2017.

1. On all pages please delete the top 2 lines (Dynavax Technologies Corporation BLA 125428/ SEQ No. 0075 and HEPLISAV™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] HEPLISAV Lot Release Protocol.
2. On pages 4 and 5 of 6 pages, Change the Endotoxin unit from EU/mL to IU/mL.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please let us know if you have any questions.

Thanks,

Sudhakar

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