

From: Agnihothram, Sudhakar
Sent: Tuesday, June 13, 2017 9:40 AM
To: 'Elaine Alambra'
Cc: Berkhausen, Katherine; Daemer, Richard J.
Subject: Information Request Regarding the Lot Release Template

Dear 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 10-May-2017.

1. On all pages
 - a. Please move the Trade Name: Heplisav-B™ to a separate line below the Licensed Name of the product.
 - b. Delete the License Number: 1883 which is under the Licensed Name of the product.
2. Please submit an example of a Lot Release Protocol with actual results.

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 submit your response by the **COB 06/19/2017**.

Please let me know if you have any questions.

Thanks,

Sudhakar

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