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To: jennifer.wellman@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Information Request
Date: Thursday, June 29, 2017 1:06:42 PM
Attachments: image001.png

(File Attachment comment)
Hello Jennifer:

We have an Information Request from our team.

Could you please provide the complete bacterial endotoxin test qualification report from (b) (4), showing the drug product matrix is suitable for the intended test method (in accordance with (b) (4)), to include maximal valid dilution (MVD), tested dilutions, positive product control percent recoveries, lot number(s), final selected testing dilution and endotoxin test results. A results table with this information (expect the MVD) was provided in the application, however, CBER is requesting the complete qualification report for review.

Would it be possible to provide this requested information by next Friday, July 7, 2017.
Thank you and please let us know if you have any questions.

Nevitt

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