

From: Morris, Nevitt
To: Paul.Gil@Sparktx.com; jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Spark / DBSQC Information Request 11/26/17
Date: Sunday, November 26, 2017 8:23:36 PM
Attachments: image001.png
Importance: High

(File Attachment comment)
Hi Paul and Jim:

We have the following DBSQC Information Request for Spark Therapeutics.
Please
provide a response back by Wednesday November 29, 2017 COB.

Please provide the complete bacterial endotoxin test qualification report from (b)(4), showing that the Diluent: Suspension for Injection (lot# (b)(4)) 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, and final selected testing dilution and endotoxin test results.

Please acknowledge receipt of this email.

Thanks,

Nevitt

Nevitt Morris

Nevitt
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