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Cc: paul.gil@sparktx.com; Morris, Nevitt  
Subject: BLA 125610 Spark Information Request DBSQC 10/03/17  
Date: Wednesday, October 04, 2017 9:43:28 AM  
Attachments: image001.png

(File Attachment comment)  
Hi Jim and Paul:

Please see the DBSQC Information Request below. We are asking for a response by next Wednesday October 11, 2017:

CBER requests that you submit both (b) (4) method and the (b) (4) method qualification reports for the drug substance to show the test samples meet their qualification acceptance criteria according to (b) (4) or (b) (4). Please provide the conformance batch numbers, (b) (4) test results data used in the study.

Thanks, and please acknowledge receipt of this email Information Request.

Nevitt

Nevitt Morris

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