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Cc: Morris, Nevitt  
Subject: BLA 125610 Spark Information Request DBSQC 10.13.17  
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Attachments:  
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Hi Jim:

Nice to meet you yesterday during the lunch break at the Advisory Committee for this BLA.

We have the following Information Request from DBSQC for Spark's response. We are asking for a turn around time of 3 weeks, but if you can provide a response sooner, that would be fine. Please acknowledge receipt of this email.

CBER expects environmental isolates to be qualified as part of your method qualification, as the indicated USP microorganism are generally representative of potential bioburden contaminants. Thus, with known environmental isolates CBER expects qualification to ensure known environmental can be detected in the tested matrix. Therefore, CBER expects known environmental isolates in both the (b) (4) and (b) (4) facilities be include in their respective method qualification (Validation) for drug substance and drug product, respective.

Thanks,

Nevitt

Nevitt Morris

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