

From: Morris, Nevitt
Sent: Tuesday, November 07, 2017 4:40 PM
To: jim.wang@sparktx.com; paul.gil@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Spark Therapeutics, Information Request CMC
11.07.17

Importance: High

Hello Jim/Paul:

We have the following CMC Information Request for your review. Please provide responses by Monday, November 13, 2017.

1. Please provide the revised MSS 10179 for HEK Master Cell Bank to accurately reflect that (b) (4) testing will be completed on all incoming lots of the MCB as agreed in amendment 25.
2. Please clarify the (b) (4) plasmid cell bank storage conditions including who has custody of the banks ((b) (4) Spark), the temperature they are stored, and the maximum length of time the plasmid cell banks are stored. Additionally, please provide supporting stability data which supports the expiration date of the plasmid cell banks and demonstrates that the banks are appropriately stored.
3. Based on information provided in the BLA it appears as though the DS lot put on the stability protocol were made about (b) (4) before the initiation of the stability study. To clarify the length of time from manufacturing to current stability testing results, please clarify the following regarding DS stability lot (b) (4) and DP stability lot (b) (4):
 - 1) The length of time from manufacturing to placement on stability study
 - 2) The temperature and location where the lots were stored or shipped from the end of manufacturing to the beginning of the stability studies.
 - 3) Whether the process for these lots typical of other manufactured lots.
 - 4) Whether the process used for handling of stability lots represent your plans for the commercial lots.

Please acknowledge receipt of this CMC Information Request.

Thanks,

Nevitt

Nevitt Morris

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