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To: jim.wang@sparktx.com; paul.gil@sparktx.com
Cc: Bi, Lilia Lei; Morris, Nevitt
Subject: BLA 125610 CMC Information Request 9.19.17
Date: Tuesday, September 19, 2017 5:12:02 PM
Attachments:
(File Attachment comment)
image001.png

Hi Jim and Paul:

Please respond to the following CMC Information Request by next Wednesday, September 27, 2017. Please acknowledge receipt of this Information Request email.

Spark BLA 125610

CMC Information Request:

1.

Please reset the acceptance criteria for the 'In vitro relative potency of

(b) (4) assay' used in Drug Product release to (b) (4) considering

the (b) (4) data from all lots manufactured to date. There is no clinical/manufacturing/comparability data to support the proposed specification limit (b) (4) .

2.

Please provide verification reports for the following compendial methods to

show suitability of the methods for rAAV-hRPE65 Drug Product Release:

a. Test for Particulate Matter: (b) (4)

b. Extractable Volume: (b) (4)

3.

Please provide an update to the ongoing validation studies for the 'In vitro

relative potency of (b) (4) assay' that is used for Drug Product release.

4.

The PPQ lots (b) (4) DP) were put on stability studies in November of 2016.

The 3-month and 6-month real time stability data were submitted to the BLA.

Please submit the 9-month real time stability data to the BLA when available.

Please note that the expiration date of your product may be based on the available real time stability data at the time of approval, if approved.

Please also

note the expiration date may be extended through BLA supplements with additional stability data.

Thanks,

Nevitt

Nevitt Morris

Nevitt
Morris,
RN,
BSN,
BS
Consumer
Safety
Officer

(Unsigned signature field (Click to sign)) Signature field is unsigned

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