

From: Morris, Nevitt
To: jennifer.wellman@sparktx.com
Cc: Morris, Nevitt; jim.wang@sparktx.com; paul.gil@sparktx.com; Ballica, Rabia; Bi, Lilia Lei; Taraporewala, Zenobia;

(File Attachment comment)

(Stamp comment

Approved Nevitt.Morris

7/24/2017 4:02:10 PM

blank)

Jones, Cecily; Allen, Ekaterina

Subject: BLA 125610 Information Request 7/24/17

Date: Monday, July 24, 2017 5:00:36 PM

Attachments: image001.png

Hi Jennifer:

We are submitting this Information Request to you:

Information Request:

Please provide the following information for the Drug Substance (DS) Manufacturing at Spark Therapeutics Inc. in PA (FEI# 3011194531):

- 1-SOP (Standard Operation Procedure) on deviations
- 2-SOP for CAPA (Corrective Action and Preventive Action)
- 3-SOP for change control
- 4-SOP on CGMP training
- 5-SOP for document control
- 6-Change Over Procedures (SOP) in shared areas (multi-product) and equipment
- 7-Segregation, labeling and tracking procedures (SOP) for shared areas and equipment to prevent mix-ups and cross contamination
- 8-SOP for cleaning/sanitization of shared/common facility areas and equipment
- 9-SOP for cleaning/sanitization of Suite 401 manufacturing DS areas and re-used equipment (dedicated to AAV2-hRPE65v2 DS)
- 10-A copy of your quality agreements with the contract drug product (DP) manufacturer ((b) (4)) and contract testing companies/laboratories (which perform release testing on AAV2-hRPE65v2 DP)

You can submit more SOPs for each of the information request items above (1-10) if there are more than one.

We are requesting a response back from Spark Therapeutics by August 2, 2017, and the response information submitted as an amendment to the file.

Please acknowledge receipt of this Information Request and let us know if you have

any questions.

Thanks,

Nevitt

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

Nevitt Morris

Nevitt
Morris,
RN,
BSN,
BS
Consumer
Safety
Officer
Office
of
Tissues
and
Advanced
Therapies
Center
for
Biologics
Evaluation
and
Research
(CBER)

U.S.
Food
and
Drug
Administration
Building
71,
Room
4207
10903
New
Hampshire
Avenue
Silver
Spring,
MD 20993
Phone: (240)
402-8269
Fax: (301)
595-1303
Nevitt.Morris@fda.hhs.gov

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