

From: Morris, Nevitt
To: jennifer.wellman@sparktx.com
Cc: Morris, Nevitt
Subject: Information Request for BLA 125610
Date: Friday, June 23, 2017 10:25:36 AM
Attachments:
(File Attachment comment)
image001.png

Dear Ms. Wellman:

Please provide a response to the CMC information request below, by June 29, 2017, if possible:

1.

Please help us locate the following information in your BLA submission:

- Complete, annotated sequences of the plasmids "pAAV2-hRPE65v2", "pAAV2PKv2", and "pAD2HPv2".

2.

Please clarify the relationships and differences between the "PPQ Acceptance Criteria" listed in your submission "3.2.S.2.5 Process Validation and or Evaluation, Table 2-Table 9", with the "MPR range" and "Filed Range/BLA range" listed in your submission "3.2.S.2.6 Manufacturing Process Development, Table 30-Table 31".

3.

Please provide a detailed plan of the continued process verification studies mentioned in 3.2.S. Drug Substance: 3.2.S.2.5 Process Validation and or Evaluation, including a study protocol, proposed production scale, and the control strategy for manufacturing process.

4. Please provide a detailed plan of the continued process verification studies mentioned in 3.2.P.

If you have any questions, please contact me at 240-402-8269 or by email at

Nevitt.Morris@fda.hhs.gov

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