

From: Morris, Nevitt
To: Jennifer.Wellman@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610
Date: Monday, June 19, 2017 3:55:29 PM
Attachments: image013.png

(File Attachment comment)
Dear Ms. Wellman:

We are reviewing your original May 16, 2017, submission to BLA 125610 for Voretigene Neparvovec. We determined that the following information is necessary to continue our review:

1. We were not able to open the following dataset legacy files for Adverse Events and Prior Concomitant Medication, under Module 5.3.5.2. Please resubmit. If additional clarification is needed, please let me know. The review of this submission is ongoing, and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by June 23, 2107, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is January 12, 2018.

Please acknowledge receipt of this request and call me at (240) 402-8269 or Nevitt.Morris@fda.hhs.gov if you have any questions.

Sincerely,

Nevitt

Nevitt Morris
Regulatory Project Manager
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
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(240) 402-8269
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(Unsigned signature field (Click to sign)) Signature field is unsigned

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