

From: Glen, Jacqueline
Sent: Friday, August 18, 2017 12:47 PM
To: jennifer.wellman@sparktx.com; Paul Gil (Paul.gil@sparktx.com)
Cc: Morris, Nevitt; Alicea, Candido
Subject: Information Request for 125610

Importance: High

Hi

The FDA is reviewing your BLA 125610. In order to complete this review we have the following information request for BLA 125610.

We note from the information provided in your BLA 125610 that (b) (4) does not monitor non-viable particles in operation during AAV2-hRPE65v2 product filling in (b) (4) because of contamination risk for particle counter with viral aerosols. Under this circumstance, non-viable particle monitoring in operation can be performed during media fill runs, because viral product is not used for media fill. Please incorporate non-viable particle monitoring in operation into your media fill protocol for (b) (4) and provide the revised protocol.

Please acknowledge receipt of this request and provide a response by August 29, 2017 at 12:00 pm (EST).

If there are any questions, feel free to contact me today or Nevitt Morris starting Monday at Nevitt.Morris@fda.hhs.gov.

Thank you
Jackie

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