

From: Paul Gil <Paul.gil@sparktx.com>
Sent: Wednesday, November 08, 2017 6:54 PM
To: Morris, Nevitt
Subject: Re: BLA 125610 Spark Therapeutics/Information Request CM 11.08.17

Hi Nevitt,
I acknowledge receipt.
Regards,
Paul

----- Original Message -----

From: "Morris, Nevitt" <Nevitt.Morris@fda.hhs.gov>
Date: Wed, November 08, 2017 4:19 PM -0500
To: Jim Wang <jim.wang@sparktx.com>, Paul Gil <Paul.gil@sparktx.com>
CC: "Morris, Nevitt" <Nevitt.Morris@fda.hhs.gov>
Subject: BLA 125610 Spark Therapeutics/Information Request CM 11.08.17
Hi Jim and Paul:

We are submitting a CMC Information Request with responses expected by November 13, 2017:

1. For the tests listed in the "Table 15 Comparability Results for Side-by-Side Testing" submitted in section 3.2.P.2.3.3.1 Evaluation of Comparability, please provide the dates that the tests were performed.
2. Please provide updated stability data for the Engineering lots (#3) (b) (4) (DP) and (b) (4) (DS) at (b) (4), listed as ongoing in Table 5 of section 3.2.P.8.1. Do you have any plans for remaining containers, if there are any?

Thanks and please acknowledge receipt of this Information Request.

Nevitt

Nevitt Morris

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