

(File Attachment comment)

From: Paul Gil

To: Morris, Nevitt

Subject: Re: BLA 125610 CMC Information Request 12.06.17 URGENT

Date: Wednesday, December 06, 2017 4:27:59 PM

Attachments: image001.png

Hi Nevitt,

I acknowledge receipt.

Thanks,

Paul

----- Original Message -----From:

"Morris, Nevitt" <Nevitt.Morris@fda.hhs.gov>

Date: Wed, December 06, 2017 3:48 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 CMC Information Request 12.06.17 URGENT

Hi Jim and Paul:

Please respond to the following CMC Information Request by email today and please have the amendment submitted to us electronically no later than this Friday December 8, 2017:

1.

How long and under what conditions is the DP stored at (b) (4)

?

2.

What are the addresses of the (b) (4) locations, and how will the product

be handled when an order is obtained for shipment?

Thanks and please acknowledge this email request.

Nevitt

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

(Document certified by Nevitt V. Morris -S <nevitt.morris@fda.hhs.gov>)
Signed by Nevitt V. Morris -S <nevitt.morris@fda.hhs.gov> Time:
2017.12.07 00:17:51 -05'00'

Fax: (301) 595-1303

Nevitt.Morris@fda.hhs.gov

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