

From: Morris, Nevitt
To: jennifer.wellman@sparktx.com
Cc: Morris, Nevitt; jim.wang@sparktx.com; paul.gil@sparktx.com
Subject: BLA 125610 Information Request (7.21.17)
Date: Friday, July 21, 2017 4:24:51 PM
Attachments: image001.png

(File Attachment comment)
Hi Jennifer:

Bla 125610 Lot Release Protocol Template

Please provide a lot release protocol template which includes the assays performed and their specifications for lot release. A response is requested three weeks post receipt of this email request.

Thanks,

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
Fax: (301)
595-1303
Nevitt.Morris@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS
ADDRESSED
AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND
PROTECTED
FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person
authorized to deliver
the document to the addressee, you are hereby notified that any review,
disclosure,
dissemination, copying, or other action based on the content of this
communication is not
authorized. If you have received this document in error, please
immediately notify the sender
immediately by e-mail or phone.
(Unsigned signature field (Click to sign)) Signature field is unsigned