

From: Morris, Nevitt
To: Jim.Wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Information Request date July 31, 2017 #1
Date: Monday, July 31, 2017 5:06:04 PM
Attachments: image003.png

(File Attachment comment)
Hi Jim:

Could you respond to the following request as soon as possible:

We could not locate the following items in the BLA submission:

.
Anti-AAV2 antibody in serum samples by Enzyme-Linked Immunosorbent Assay
(ELISA) for Study 101 and Study 102
.
RPE65-Specific antibody by ELISA for Study 301 and Study 101
.
PBMC Interferon-
Responses to AAV2 and RPE65 by an Enzyme-Linked

Immunospot Assay (ELISPOT) in peripheral blood mononuclear cells (PBMC)
for

Study 101 and Study 102

Thanks, and please acknowledge receipt of this email request.

Thanks again,

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
(Unsigned signature field (Click to sign)) Signature field is unsigned

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.

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.

