

From: Morris, Nevitt
To: jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Clinical Information Request 8.22.17
Date: Tuesday, August 22, 2017 11:28:22 AM
Attachments: image001.png

(File Attachment comment)
Hi Jim:

We are submitting the following Information Request from our clinical team regarding BLA 125610.
Please respond accordingly.

Clinical Information Request:

We will use the term "MLMT score change" instead of "MLMT change score" (Applicant's term) to describe the difference between the MLMT score at baseline and the MLMT score at a follow-up visit in both our Advisory Committee (AC) meeting briefing document and presentation slides for BLA 125610. We feel that the term "MLMT score change" is easier for the AC members and audience to understand. We hope that the Applicant will adopt the term and modify their document and presentation slides accordingly.

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

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