

From: Morris, Nevitt
To: Jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Information Request re: AC question 10.04.17
Date: Thursday, October 05, 2017 10:06:44 AM
Attachments: image001.png
Importance: High

(File Attachment comment)
Hi Jim:

The clinical team had the following Information Request (highlighted in Yellow) that needed clarification at your earliest convenience:

Please clarify the following regarding the size of the navigation course:

In your AC briefing document, the mobility course is described as each measuring 5' x 10' (Page 50 of 149)
In your Summary of Clinical Efficacy (Module 2.7.3), the MT course was described as 7' x 12' (with one-foot border, Page 68).

Which size should be used in the AC presentation?

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

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.

