

Tilghman, Tracy

From: Linda Zuckerman <Linda.Zuckerman@THEMEDCO.com>
Sent: Monday, December 08, 2014 4:43 PM
To: Tilghman, Tracy
Cc: Sabrina Gu
Subject: RE: Update to Teleconference with ProFibrix - December 8, 2014

Hi Tracy,

Thanks for your prompt response on this – we will make the amendment to the BLA accordingly. Have a good rest of the day-

-Kind regards

Linda

Linda Zuckerman, Ph.D.

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From: Tilghman, Tracy [<mailto:Tracy.Tilghman@fda.hhs.gov>]
Sent: Monday, December 08, 2014 13:32
To: Linda Zuckerman
Subject: Update to Teleconference with ProFibrix - December 8, 2014

Dr. Zuckerman:

After internal discussion, the FDA agrees that the best way to implement the changes related to (b) (4) assay is to submit single amendment including the following:

1. Cover letter officially informing the FDA that the ProFibrix removes the assay. Please reference today's teleconference and our agreement to this change in the letter.
2. Amended BLA modules.

Please let me know if you have any questions or require clarification on the information above.

Sincerely,

LT Tracy Tilghman, MPH, CHES

Blackberry: (b) (4)
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