Tilghman, Tracy

From: Tilghman, Tracy
Sent: Wednesday, September 10, 2014 12:45 PM
To: Linda Zuckerman (Linda.Zuckerman@THEMEDCO.com)
Subject: Reference BL# 125523/0 - Information Request

Importance: High

Reference BL#125523/0

Dear Dr. Zuckerman,

We are reviewing your January 31, 2014 original submission for Fibrin Sealant, Human Fibrinogen, Human Thrombin indicated as an aid to surgical hemostasis for mild to moderate bleeding from small vessels when control of bleeding by standard surgical techniques is ineffective or impractical. We request the following additional information to continue our review:

1. Your Justification of Specification for Raplixa drug product is insufficient. Please revise the ranges and limits for quantitative parameters in the specification based on the data acquired from testing of drug product lots manufactured up to date. Please submit the complete set of data used for justification of specification and the statistical analyses employed.

Please submit this information request as an amendment to this submission by October 1, 2014. If you are unable to respond by September 1st, please contact me at your earliest possible convenience.

The review of this submission is ongoing and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for this file is January 31, 2015.

If you have any questions, please contact me at (240) 402-8376.

Sincerely,

LT Tracy Tilghman, MPH, CHES
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