

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Tuesday, April 22, 2014 4:19 PM
To: Linda Zuckerman (Linda.Zuckerman@THEMEDCO.com)
Subject: Reference BL# 125523/0 - Information Request

Importance: High

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. Please provide at least (b) (4) of Spray dried thrombin ((b) (4)) referenced in SOP 1838, Version 02.

Please ship reagents to the address listed below:

Catherine Poole
Regulatory Coordinator
Division of Biological Standards and Quality Control (DBSQC)/OCBQ/CBER/FDA
NLRC Bldg. B, Room 2411
5516 Nicholson Lane
Kensington, MD 20985

Please submit this information request as an amendment to this submission by May 13, 2014. If you are unable to respond by May 13th, 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 (301) 827-9427.

Sincerely,

LT Tracy Tilghman, MPH, CHES
Lieutenant, United States Public Health Service
Regulatory Project Manager
U.S. Food & Drug Administration
CBER/OBRR/IOD
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RM 556N, HFM-380

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