

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Tuesday, July 22, 2014 10:52 AM
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 indicate why the results for (b) (4) for thrombin (b) (4) for PPQ batches are reported as (b) (4) when the acceptance criteria is noted as (b) (4) as referenced in Table 12: In-Process Controls taken during Thrombin (b) (4) Preparation in Section 5.7.2 of validation report PRO 1066. In addition, please include an explanation for the same discrepancy also reported for fibrinogen (b) (4) results for PPQ batches (results of (b) (4) in Table 13: In-process Controls Taken during Fibrinogen (b) (4) Preparation in report PRO 1066.

Please submit this information request as an amendment to this submission by August 5, 2014. If you are unable to respond by August 5th, 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

Lieutenant, United States Public Health Service

Regulatory Project Manager

U.S. Food & Drug Administration

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