

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Monday, August 25, 2014 4:28 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:

Regarding your validation report (MVR-120-02) for the method for Analysis of Fibrinogen (b) (4) using a (b) (4) Assay,

1. You have not formally validated Specificity of your method. Please provide appropriate experimental data to demonstrate Specificity of your method and exclude matrix interference.
2. You have evaluated Accuracy of your method using (b) (4) In Module 3.2.P.5, Table 6, it is stated that Accuracy was validated in the (b) (4) solution, however it is not reflected in the Validation Report. Please confirm that Accuracy was validated in the (b) (4) solution and provide details of the validation procedure including the (b) (4) solution composition. Please provide justification that your approach (i.e., using (b) (4) standard but not the actual product) can be considered adequate to evaluate Accuracy.

Please submit this information request as an amendment to this submission by September 8, 2014. If you are unable to respond by September 8th, 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

CBER/OBRR/IOD

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