

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Monday, March 31, 2014 3:52 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. The submission does not indicate that levels of Trehalose (b) (4) and Calcium Chloride (b) (4) are tested or controlled in the final product. Please commit to the adoption of drug product specifications for these components along with the adoption and validation of appropriate test methods. Please indicate a time frame for the submission of procedures, validations and batch analytical results.

Regarding other products manufactured in the (b) (4) facility, please provide the following:

2. A comprehensive list of all additional products to be manufactured or manipulated in the areas used for the manufacture of fibrin sealant.
3. A brief description of the type and developmental status (including pre-clinical and investigational) of the additional products.
4. A list in which rooms the additional products will be introduced, the manufacturing steps that will take place in the rooms, and whether additional products are introduced on a campaign basis or concurrently during the manufacture of fibrin sealant.
5. A list of additional products that may share product contact equipment with the fibrin sealant if plasma is non- US sourced, and indicate dedicated versus multi-use equipment for each process step.

Please submit this information request as an amendment to this submission by April 14, 2014. If you are unable to respond by April 14th, 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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