

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Tuesday, April 15, 2014 12:06 PM
To: Linda Zuckerman (Linda.Zuckerman@THEMEDCO.com)
Subject: Reference BL# 125523/0 - Information Request
Attachments: Lot Release Protocol for 125523.doc

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:

We are reviewing your January 31, 2014 biologics application (BLA) for Fibrin Sealant, Human Fibrinogen Human Thrombin. We determined the following information is necessary to continue our review:

1. Please provide (b) (4) vials per lot from each of the following lots: (b) (4) .
2. Please provide (b) (4) vials from lot (b) (4) .
3. Samples should be sent to the address listed below and should be accompanied by a Concurrent Testing Letter. A template of the Concurrent Testing Letter has been provided on page 2 of this information request.

Sample Custodian (ATTN: HFM-672)
Center for Biologics Evaluation and Research
Bldg: NLRC-B, Room 113
5516 Nicholson Lane
Kensington, MD 20895

4. Please provide (b) (4) in an amount sufficient to run at least 3 analyses sessions (standard, control and (b) (4) lots of sample).
5. 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
6. Please submit a draft Lot Release Protocol Template as an amendment to the BLA file. Templates for the Lot Release Protocol are attached to this information request.

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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