

## Tilghman, Tracy

---

**From:** Tilghman, Tracy  
**Sent:** Tuesday, September 11, 2012 3:19 PM  
**To:** 'Chung, Jessica [ETHUS]'  
**Cc:** Shields, Mark  
**Subject:** Reference BL# 125392/0 - Information Request

**Importance:** High

**Attachments:** STN 125392 EVARREST PI revisions 9 11 2012 LN\_KL\_NA (1).doc



STN 125392  
VARREST PI revisio.

Dear Ms. Chung,

We are reviewing your March 30, 2012 resubmission for Fibrin Pad to be used as an adjunct to hemostasis for soft tissue bleeding during retroperitoneal, intra-abdominal, pelvic, and (non-cardiac) thoracic surgery when control of bleeding by standard surgical methods of hemostasis is ineffective or impractical. We request the following information to continue our review:

1. Please submit both a red-line and clean version of the 9.11.2012 PI revisions as a WORD file.

Please respond to this request as an amendment to this file, referencing the date of this request by September 18, 2012.

The review of this submission is ongoing and issues may be added, expanded upon, or modified as we continue to review this submission.

The resubmission action due date for this file is September 29, 2012.

If you have any questions, please contact me at (301) 827-9427.

Sincerely,

Tracy Tilghman, MPH  
Lieutenant, United States Public Health Service  
Regulatory Project Manager  
U.S. Food & Drug Administration  
CBER/OBRR/DBA/RPMB  
1401 Rockville Pike  
RM 556N, HFM-380  
Rockville, MD 20852  
Phone: 301-827-9427  
Email: tracy.tilghman@fda.hhs.gov

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the

document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone."