

## Tilghman, Tracy

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**From:** Tilghman, Tracy  
**Sent:** Thursday, November 29, 2012 1:19 PM  
**To:** Chung, Jessica [ETHUS]  
**Cc:** Ananyeva, Natalya; Lindsey, Kimberly  
**Subject:** Reference BL# 125392/0 - Information Request

**Importance:** High

**Attachments:** STN 125392 EVARREST PI Revisions 11 29 2012 Track Changes.doc; STN 125392 EVARREST Carton Label\_29 Nov 2012.pdf



STN 125392



STN 125392

VARREST PI Revisio VARREST Carton Lab

Dear Ms. Chung,

We are reviewing your October 9, 2012 resubmission for Fibrin Sealant Patch to be used as an adjunct to hemostasis for soft tissue bleeding during open retroperitoneal, intra-abdominal, pelvic, and non-cardiac thoracic surgery when control of bleeding by standard surgical methods of hemostasis is ineffective or impractical. Attached is the annotated text of the Prescribing Information (PI) and the package label. We request the following information to continue our review:

1. Please revise the attached documents accordingly. The edits discussed during the November 28, 2012 teleconference were found to be adequate and minor additional edits were made in pp. 1, 3, 6-9, and 11.
2. In the package label, please follow the comment sign and add "Absorbable Patch" in the red field under 4 inch X 4 inch line.

Please submit both annotated and clean versions of the revised Prescribing Information as WORD files and as PDF files. In addition, please include the revised package label in PDF format.

Please respond to this request as an amendment to this file, referencing the date of this request, by November 29, 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 December 9, 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  
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