

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Wednesday, August 08, 2012 4:38 PM
To: 'Chung, Jessica [ETHUS]'
Cc: 'Dauria, Raina [ETHUS]'; Shields, Mark
Subject: Reference BL# 125392/0 - Information Request

Attachments: STN 125392_General comments for EVARREST PI_8AUG2012.pdf; STN 125392_EVARREST PI_8AUG2012.doc



STN
_EVARREST PI_8AU

ear 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 below to continue our review:

1. Please revise the text of Prescribing Information (PI) and carton and container labels according to FDA recommendations and annotated version of the PI. Please submit the revised version as an amendment to the BLA as a courtesy copy by e-mail by August 23, 2012.

Please respond to this information request as an amendment to this file, referencing the date of this request by August 23, 2012. If you anticipate you will not be able to respond by August 23rd, please contact me immediately so a new response date can be identified.

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
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Regulatory Project Manager
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