

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Friday, November 16, 2012 9:17 AM
To: 'Chung, Jessica [ETHUS]'
Subject: Reference BL# 125392/0 - Information Request

Importance: High

Attachments: STN 125392 EVARREST PI_11 15 2012_annotated.doc



STN 125392
VARREST PI_11 15 2

ear 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. We request the following revisions to the PI to continue our review:

1. Please revise the description of the immunogenicity assessment of EVARREST, section 6, page 8, for better clarity.
2. Please correct the position of Pseudorabies Virus in Table 3, section 11 DESCRIPTION.
3. Please incorporate other typographical edits and proof-read the whole document for accuracy.

Please submit both a red-line and clean versions of the revised Prescribing Information as WORD files and as PDF files.

Please respond to this request as an amendment to this file, referencing the date of this request, by November 19, 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
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