

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Tuesday, August 8, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, August 03, 2017 5:02:00 PM
Attachments: [image001.png](#)
Importance: High

Dear Ms. Robertson:

We are reviewing your original November 3, 2016, submission to BLA 125640 for Fibrin Sealant (Human). We determined that the following information is necessary to continue our review:

Please provide appropriate information comparing thrombogenicity of FS Grifols to that of Surgicel in the submitted studies IG1102 and IG1103.

Specifically, please provide information on deep venous thrombosis, pulmonary thrombosis, and myocardial infarction.

Preferred Term	FS Grifols N=500 n (%)	Surgicel N=320 n (%)	Manual Compression N=57 n (%)
Respiratory failure	6 (1.2)	1 (0.3)	0
Renal failure acute	5 (1.0)	1 (0.3)	0
Anemia	2 (0.4)	4 (1.3)	0
Myocardial infarction	2 (0.4)	0	1 (1.8)
Postoperative wound infection	2 (0.4)	0	1 (1.8)
Hemorrhagic anemia	1 (0.2)	0	1 (1.8)
Pyrexia	1 (0.2)	0	1 (1.8)
Vascular graft thrombosis	1 (0.2)	0	1 (1.8)
Deep Venous thrombosis			
Pulmonary Embolism			
Parvovirus infection			

The review of this submission is ongoing, and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by August 8, 2017, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

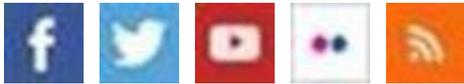
If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is November 3, 2017.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov if you have any questions.

Sincerely,

Yu Do, M.S.
Regulatory Project Manager
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
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