

From: [Do, Yu](#)
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Tuesday, October 3, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Monday, October 02, 2017 4:22:03 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 have the following comment and requests for additional information to continue our review:

1. Please enumerate, by subject number, each FS Grifols-exposed subject in Study IG1101, Study IG1102, and Study IG1103 for whom TEAE of “pulmonary embolism” was reported. Please include all subjects for whom this TEAE was reported, regardless of seriousness designation or investigator’s treatment attributability designation.

Additionally, with reference to the submitted Integrated Summary of Safety, incidence of “pulmonary embolism” is reported for 6 subjects (5211017, 2012007, 2012020, 6002024, 2322036, and 3253006) as 2 (0.4%) in Table 7-4 and 4 (0.8%) in Table 7-9. Please account for this discrepancy.

2. Please enumerate, by subject number, each FS Grifols-exposed subject in Study IG1101, Study IG1102, and Study IG1103 for whom TEAE of “myocardial infarction” was reported. Please include all subjects for whom this TEAE was reported, regardless of seriousness designation or investigator’s treatment attributability designation.
3. Please enumerate, by subject number, each FS Grifols-exposed subject in Study IG1101, Study IG1102, and Study IG1103 for whom TEAE of “deep vein thrombosis” was reported. Please include all subjects for whom this TEAE was reported, regardless of seriousness designation or investigator’s treatment attributability designation.
4. Please enumerate, by subject number, each FS Grifols-exposed subject in Study IG1101, Study IG1102, and Study IG1103 for whom TEAE of “vascular graft thrombosis” was reported. Please include all subjects for whom this TEAE was reported, regardless of seriousness designation or investigator’s treatment attributability designation.

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 October 3, 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.

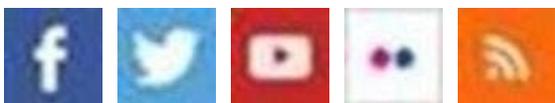
The action due date for this file is November 3, 2017.

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.
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