

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Thursday, September 7, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, August 31, 2017 3:56:00 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 have the following comment and request for additional information to continue our review:

In Study IG1102, there were seven deaths reported after exposure to FS Grifols fibrin sealant. Your response dated August 29, 2017, included narrative reports only on four of the patients.

Please supply information on the details of the surgery performed (liver resection for carcinoma, liver resection for benign process, etc.), details on the cause of death, and the day after exposure to FS Grifols on which the death has occurred. Please supply operative reports if available. Also, please provide the patient IDs used to identify patients in the study.

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 September 7, 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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