

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Friday, March 24, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Monday, March 20, 2017 10:13:00 AM
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 comments and requests for additional information at this time:

This is in reference to information provided on March 1, 2017, with your samples for testing:

1. Regarding your February 23, 2017, response to Information Request dated January 31, 2017, please provide the Certificate of Analysis/qualified potency values for the following:
 - a. Thrombin in-house working reference material as standard, as detailed in Section 4.1 of IG_MA-000457A_ING
 - b. Thrombin in-house working reference material as control, as detailed in Section 4.1 of IG_MA-000457A_ING
 - c. Fibrinogen control, as per Section 4.2 of Method IG_MA-000158E_ING
2. You have provided two lots of thrombin secondary reference standard with batch numbers (b) (4) . Please indicate which one is the standard and which one is the control for your thrombin assay. Please provide the assigned thrombin potency values for both thrombin reference standards.

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 March 24, 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

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