

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Thursday, April 13, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, March 30, 2017 2:27:00 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 comments and requests for additional information at this time:

1. You stated, "The surgeon must push the plunger link with a maximum force of (b) (4) to allow the solutions to flow and form the fibrin clot in situ," while you did not specify the Initiating (breaking loose) and Sustaining (gliding) Force requirements. Please provide the Initiating and Sustaining Force specification and verification.
2. In Section 3.2.P.5.1, you provided the specifications for fill volume of the drug product components. In order to show the dose delivery and efficiency/accuracy of the delivered volume, please provide container content (delivered volume) study for both components of the drug product (fibrinogen and thrombin).
3. In your response to Information Request dated March 7, 2017, you stated that biocompatibility aspects of the combination product have been covered in PRS-152 in agreement with ISO 10993.

Please submit a full biocompatibility report for the plastic syringe holder or provide a cross-reference if it is included in the dossier.

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 April 13, 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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Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

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