

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Wednesday, September 20, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, September 05, 2017 12:54:00 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:

According to FDA guidance for industry [Q1A\(R2\) Stability Testing of New Drug Substances and Products](#), Section Specification (2.2.5), stability studies should cover testing of those attributes of the drug product that are susceptible to change during storage and are likely to influence quality, safety, and/or efficacy, which include functionality tests for a dose delivery system. The proposed combination product will go through dramatic temperature change (being stored at lower temperature than -18 °C and thawed to use), which will likely affect the essential performance requirements of the syringe. However, your stability testing did not include the essential performance requirements of the syringe, such as dose accuracy and functionality of the syringe, including break loose force and gliding force.

Please provide a justification for how you have demonstrated, or plan to demonstrate, that the device still meets the essential performance requirements after its intended shelf-life and use-life.

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 20, 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
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