

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: URGENT Information Request (Response Due by TODAY, December 27, 2016): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, December 27, 2016 11:35:00 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 determined that the following information is necessary to continue our review:

1. This is in reference to your Amendment 8 dated December 23, 2016:

You stated that two additional lots for In-Support Testing will be manufactured during the time of the planned Pre-License Inspection (PLI), and the product will be release-tested by week 18 of 2017.

Please let us know if it is possible to start the manufacture for our In-Support Testing earlier and have the two lots available by early to middle of April 2017 instead (as discussed during the December 7, 2016, teleconference), i.e., separate from the time of the planned PLI.

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 December 27, 2016, 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
Center for Biologics Evaluation and Research
Office of Medical Products and Tobacco
Food and Drug Administration
(240) 402-8343
Yu.Do@fda.hhs.gov



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