

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Responses Due by December 27, 2016, for Items 1 and 2 and January 11, 2017, for Items 4 and 5): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, December 15, 2016 5:09:00 PM
Attachments: [image007.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. Please specify your plan and timeline for the manufacture and release testing of two lots of Fibrin Sealant Grifols (in addition to Lot IBND6L3MP1) for in-support testing by FDA.
2. Please submit reports from the Human Factors/Usability studies for the assembled Final Drug Product, or indicate location of associated documents with relevant information and analysis in your BLA submission.
3. We note that the Final Drug Product is composed of two syringes assembled on the syringe holder. Please:
 - a. Describe the format of the samples that will be provided to the Agency for in-support testing.
 - b. Provide instructions or relevant SOP on how this sample format(s) should be handled to allow for release testing of individual components (Human Fibrinogen and Human Thrombin) as well as the Functionality test involving both biological components.
 - c. Provide your Sampling Plan for release testing of the Final Drug Product and state sample volumes required for each test.
4. Please submit validation reports on the Final Drug Product assembly (i.e., following aseptic filling of the syringes and including assembly with the syringe holder, plungers, and plunger link), or indicate location of these reports (with report numbers) within the BLA 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 responses as an amendment to this file by December 27, 2016, for Items 1 and 2 and by January 11, 2017, for Items 4 and 5, 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



"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."