

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Wednesday, March 1, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, February 23, 2017 4:20:00 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 determined that the following information is necessary to continue our review:

1. Please provide 10 samples of the following conformance lot of Fibrin Sealant (Human):

IBND6L3MP1, 10 mL (Date of Manufacture: April 28, 2016)

This lot should be representative of the manufacturing process to be used for lots intended for interstate commerce.

2. Please provide the following standards and reagents for test methods IG_MA-000457A_ING "Thrombin Evaluation by Coagulation Using (b) (4)" and IG_MA-000158E_ING "(b) (4) in Fibrinogen by (b) (4)":
 - a. Thrombin in-house working reference material as standard (as detailed in Section 4.1 of IG_MA-000457A_ING): 2 vials with COA
 - b. Thrombin in-house working reference material as control (as detailed in Section 4.1 of IG_MA-000457A_ING): 2 vials with COA
 - c. Fibrinogen control as per Section 4.2 of Method IG_MA-000158E_ING: 2 vials with COA
3. Please provide the most recent test results, along with the test date, for the lot submitted.
4. The samples and reagents should be shipped to:

Grainne Tobin
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Division of Biological Standards and Quality Control
10903 New Hampshire Avenue
WO75, G634
Silver Spring, MD 20993-0002

These samples and documentation should be provided to CBER no later than March 1, 2017. If this is not feasible, please notify CBER when the shipment may be expected. Please contact Varsha Garnepudi (240-402-9547) or Grainne Tobin (240-

402-7424) if you have any questions regarding the shipment.

The review of this submission is ongoing, and issues may be added, expanded upon, or modified as we continue to review this submission. Once again, please submit your response as an amendment to this file by March 1, 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
Center for Biologics Evaluation and Research
Office of Medical Products and Tobacco
Food and Drug Administration
(240) 402-8343
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