

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Tuesday, June 13, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Friday, June 02, 2017 3:15:00 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 the following conformance lots of Fibrin Sealant (Human):
 - a. B4YBB00021, 4 mL (March 2017), 10 samples (i.e., packages with pre-filled syringes)
 - b. A4YCB00021, 6 mL (March 2017), 10 samples (i.e., packages with pre-filled syringes)

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

2. Reagents for test methods IG MA-00457A_ING "Thrombin Evaluation by Coagulation using (b) (4)" and IG MA-000158E_ING "(b) (4)" in Fibrinogen by (b) (4)"

Please provide the following standards and reagents:

- 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

The samples and reagents should be shipped to:

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

Please contact Varsha Garnepudi (240-402-9547) and/or Grainne Tobin (240-402-7424) for 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. Please submit these samples, reagents, and documentation by June 13, 2017, or notify CBER as to when the shipment should be expected via an amendment to this file. 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.

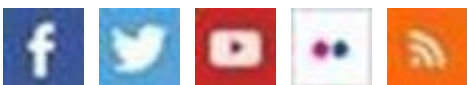
If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

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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