

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due Also by Wednesday, April 26, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Wednesday, April 19, 2017 9:33:00 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. You have submitted the subgroup analyses by age group and sex for Study IG1101. Please also provide the subgroup analysis by race group using the ITT analysis set.
2. You have submitted the subgroup analyses by age group for Study IG1102 and IG1103. Please also provide the subgroup analyses by race group and sex using the ITT analysis set.

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 April 26, 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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