



**U.S. FOOD & DRUG
ADMINISTRATION**

Memorandum

DATE September 19, 2017

TO Natalya Ananyeva, Ph.D., Chairperson

FROM Bhanu Kannan, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Telephone: 240-402-8979 Fax: 301-595-1304

THROUGH Dennis Cato, Chief, Bioresearch Monitoring Branch

THROUGH Carrie Mampilly, M.P.H., Director, Division of Inspections and Surveillance

SUBJECT Bioresearch Monitoring Summary Memo
APPLICANT: Instituto Grifols S.A.
Biologics Licensing Application (BLA): STN125640/0
PRODUCT: Fibrin Sealant (human)

Review summary statement

Bioresearch Monitoring (BIMO) inspections of two domestic, and two foreign clinical investigator sites did not reveal substantive problems impacting the data submitted in support of this Biologics Licensing Application (BLA).

Background

Four clinical investigators (CI) were inspected in support of this BLA. The inspections were conducted in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. The inspection assignments were issued for two study protocols, IG1101 and IG1103:

A Prospective, Single-blind, Randomized, Phase III Study to Evaluate the Safety and Efficacy of Fibrin Sealant Grifols (FS Grifols) as an Adjunct to Hemostasis during Peripheral Vascular Surgery- Study IG1 101

A Prospective, Single-blind, Randomized, Phase III Study to Evaluate the Safety and Efficacy of Fibrin Sealant Grifols (FS Grifols) as an Adjunct to Hemostasis During Soft Tissue Open Surgeries- Study IG1 103

The inspection assignments included specific questions concerning the respective study protocols and verification of the study data submitted in the BLA to source documents.

The CI inspections covered approximately 22% and 19% of the total subjects enrolled in study protocols IG1101 and IG1103, respectively.

The BIMO inspections were conducted at the following clinical sites:

Study	Site Number	Study Site	Location	Form FDA 483 issued	Status
IG1 101	407	Shoals Clinical Research	Florence, Alabama	No	NAI
IG1 101	521	University of Belgrade Institute for Cardiovascular Diseases, Clinic for Vascular Surgery	Belgrade, Serbia	No	NAI
IG1 103	322	Lotus Clinical Research, LLC.	Pasadena, California	No	NAI
IG1 103	722	Clinical Center of Serbia, Urology Clinic	Belgrade, Serbia	No	NAI

NAI-No Action Indicated

Financial Disclosure

The Clinical Investigator Compliance Program directs the FDA investigators to ask the clinical investigator if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouses and dependent children, and if and when the information was updated. The information submitted to the BLA was verified for the personnel at the inspected clinical sites and found no deviations.

Sponsor Issues

None noted.

Noteworthy inspectional findings

None noted.

BMB administrative follow-up

Information letters were issued to the clinical investigators inspected in support of this BLA. Should you have any questions about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 240-402-8979.

Bhanu Kannan
Consumer Safety Officer

Electronic Copies

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STN125640/0 Application folder

Chairperson

Clinical reviewer

RPM

History:

Kannan draft: 09/18/17

Drabick:09/18/2017