Our STN: BL 125640/220

SUPPLEMENT APPROVAL/
PMR FULFILLED
September 27, 2024

Instituto Grifols, S.A.
Attention: Kelly Smith
Grifols Shared Services North America, Inc.
8368 U.S. Highway 70 West
Clayton, NC 27520

Dear Kelly Smith:

We have approved your request received July 4, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Fibrin Sealant (Human) [Vistaseal] to expand the indication to include pediatric patients aged < 18 years.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: 03461406, 01662856, 01731938, and 01754480.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We approved the draft content of labeling Package Insert on September 20, 2024, submitted under BL 125640/167 amendment 10, dated September 19, 2024.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on September 19, 2024. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125640 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement (PMR) #1 identified in the November 1, 2017 approval letter for STN BL 125640/0 for Fibrin Sealant (Human). The requirement addressed in this submission is as follows:

1. Instituto Grifols, S.A. commits to evaluating the safety and efficacy of FIBRIN SEALANT (Human) as an adjunct to hemostasis during surgery in pediatric patients < 18 years of age in the deferred pediatric clinical trial under protocol IG1405 entitled “A Prospective, Randomized, Active-Controlled, Single-blind, Parallel Group Clinical Trial to Evaluate the Safety and Efficacy of Fibrin Sealant Grifols (FS Grifols) as an Adjunct to Haemostasis during Surgery in Paediatric Subjects.”

Instituto Grifols, S.A. also commits to conducting a study of the Human Factors assessment as part of the pediatric trial. The timelines for the combined PREA PMR study are as follows:

Final Protocol Submission Date: March 30, 2018

Study Completion Date: June 30, 2023

Final Report Submission Date: June 30, 2024

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Patroula Smpokou, MD
Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research