

Our STN: BL 125640/0

**PROPRIETARY NAME UNACCEPTABLE**

February 3, 2017

Instituto Grifols, S.A.  
Attention: Joan Robertson  
Vice President, Regulatory Affairs  
Grifols Shared Services North America, Inc.  
8368 U.S. Highway 70 West  
Clayton, NC 27520

Dear Ms. Robertson:

We have reviewed your November 15, 2016, amendment to your Biologics License Application (BLA) for Fibrin Sealant (Human), requesting a proprietary name review for VERASEAL.

In consultation with the Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, VERASEAL is unacceptable for the following reasons:

1. Your proposed name, VERASEAL, is considered misleading or fanciful within the meaning of 21 CFR 201.10(c)(3), 202.1(e)(5)(i), and 202.1(e)(6)(i). The proposed proprietary name, VERASEAL, may overstate the efficacy of your product by implying that it will serve as an absolute sealant in all procedures where it is utilized.
2. Your proposed name may cause medication errors due to its high phonetic and orthographic similarity to other currently marketed products within the meaning of 21 CFR 201.10(c)(5). VERASEAL is identical to that of a face mask breathing device VERASEAL®, used in acute care medical settings, and it is also phonetically and orthographically similar to other proprietary names, including those of medicinal products such as VIRASAL, KERASAL, and VIRAZOLE.

Furthermore, the name VERASEAL is highly similar to Vericel, the name of a sponsor who has an approved cell therapy product. This generates a high tendency to refer to the product by the sponsor's name rather than its proprietary name, posing a potential additional risk of medication errors.

You may submit a new proprietary name for our consideration. Any proposed proprietary name(s) should comply with the regulations regarding false, misleading, or fanciful names and phonetic or orthographic similarities to other medicinal products.

If you require additional information on developing proprietary names for drugs, we refer you to the guidance for industry *Best Practices in Developing Proprietary Names for Drugs* and guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*.

You may request reconsideration of VERASEAL by submitting a written rebuttal with supporting data or submitting a request for a Type C meeting within 60 days to discuss the initial decision. Additional information regarding submission of a meeting request may be found in the guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (March 2015).

If you have any questions, please contact the Regulatory Project Manager, Yu Do, at (240) 402-8343 or Yu.Do@fda.hhs.gov.

Sincerely,

Ramani Sista, PhD  
Director  
Division of Regulatory Project Management  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research