

RECORD OF TELEPHONE CONVERSATION

Submission ID: BL 125640/0
Review Office: Office of Tissues and Advanced Therapies (OTAT)
Product: Fibrin Sealant (Human)
Proposed Proprietary Name: VERASEAL
Proposed Indication: An adjunct to hemostasis for mild to moderate bleeding in adults (b) (4) undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. Fibrin Sealant (Human) is effective in heparinized patients.
Applicant: Instituto Grifols, S.A. (IG)

Date/Time: April 25, 2017, 10 AM, EDT
Initiated by FDA? No.
Telephone Number: 1-800-715-9436, Meeting Number *9193597128*
Author: Yu Do
Purpose: To provide clarification with regard to the outcome of CBER's review of the proposed proprietary name VERASEAL.

FDA Participants:

Yu Do, MS, RPMBI/DRPM/OTAT/CBER
Agnes Lim, MD, GMBI/DCEPT/OTAT/CBER
Lisa Stockbridge, PhD, APLB/DCM/OCBQ
Oluchi Elekwachi, PharmD, APLB/DCM/OCBQ
Alpita Popat, PharmD, APLB/DCM/OCBQ

IG Participants:

Joan Robertson, Vice President, Regulatory Affairs, Bioscience, Grifols Shared Services, NA
Patrick Lynch, Director, Global Marketing – Biosurgery

Amendment(s): Amendment 2 submitted on November 15, 2017

Summary of Discussion

The applicant stated that proprietary name VERASEAL was submitted for review during the IND stage and found to be acceptable by FDA in August 2014. Furthermore, some of the names, noted in the February 3, 2017, Proprietary Name Non-Acceptance letter, existed in 2014 when the request for this name was initially submitted. The applicant maintained that these names should have been excluded from consideration with regard to their BLA Proprietary Name Review request that was submitted on November 15, 2016.

FDA stated that there are multiple problems associated with the proposed name, VERASEAL, from both promotional and safety standpoints. The decision regarding acceptability of the name, VERASEAL, when submitted for review under IND in 2014, was conditional and contingent upon further review during review of the marketing

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application. To be exact, the recommendation issued at the IND stage, regarding the name VERASEAL, was “acceptable at this time.” The data submitted at that time were inadequate to make precise predictability of the misleading nature of the name, which has the potential interpretation that the product use results in 100% hemostatic effectiveness (i.e., *true* seal). Also, many of the potentially similar names compared during the BLA review were not available at that time. Moreover, the Phonetic and Orthographic Computer Analysis (POCA) system, used to select names with similarity from a database, has been updated and further developed, since the time of the IND review of the name, with validated algorithms to make the analysis more comprehensive. For example, POCA has been revised to assign weight on certain string placement in a name based on validated data collected over the last ten years from reported cases of medication errors. As a result, there are more moderate and highly similar names generated than before. Highly similar names (names with similarity scores of 70% or over) have been shown to cause medication error regardless of mitigation strategies.

Two other issues leading to the rejection of the name are the existence of an identical name, Veraseal, for a medical device that has potential use in the same environment and patient population as the fibrin sealant and the recent approval of MACI, a cell therapy product manufactured by the corporation Vericel. This particular product is often referred to by its manufacturer’s name rather than its proprietary name. This “coined name” poses significant additional risks of medication errors.

FDA noted that IG has the option to have branding consulting firms, such DSI and Addison-Whitney, vet the proprietary name(s) prior to submission to FDA.

FDA asked the applicant to submit any other names with POCA match percentage score of less than 70% as an alternative name for review. Moderately similar names (names with similarity scores between 50% and 69%) would require a significant difference in dosage form and strength to mitigate medication errors. Similarly named drug products with these overlapping characteristics represent an area of concern for the Agency. FDA suggested that, if the applicant desires a proprietary name prior to approval (a proprietary name is not a requirement for approval), then they should submit their alternative proprietary name as soon as possible, as this BLA has reached its mid-cycle point of the review cycle.

The applicant expressed skepticism in their ability to develop and submit an alternative name for review in time for labeling negotiation during this BLA review cycle. The applicant also expressed understanding that a proprietary name is not required for approval, and they may exercise that option if need be.

FDA stated that the Agency will make every effort to expedite the review within a given 90-day review clock.

As an additional resource, FDA offered to provide a copy of a published article that addresses similarities of proprietary name for prescription drugs. The applicant thankfully accepted the offer.

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Signature: _____

Drafted: Yu Do/April 26, 2017

Reviewed: Lisa Stockbridge/April 27, 2017

Reviewed: Oluchi Elekwachi/April 26, 2017

Reviewed: Agnes Lim/April 27, 2017

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