

## RECORD OF TELEPHONE CONVERSATION

**Submission ID:** BL 125640/0  
**Review Office:** Office of Tissues and Advanced Therapies (OTAT)  
**Product:** Fibrin Sealant (Human), FS Grifols  
**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. VeraSeal is effective in heparinized patients.  
**Applicant:** Instituto Grifols, S.A. (IG)

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**Date/Time:** December 07, 2016, 10 AM, EST  
**Initiated by FDA?** Yes.  
**Telephone Number:** 1-800-715-9436, Meeting Number (b) (4)  
**Author:** Yu Do  
**Purpose:** To discuss the availability of Drug Product lots within the shelf-life for in-support testing by CBER during the BLA review.

**FDA Participants:**  
Yu Do, MS, RPMBI/DRPM/OTAT/CBER  
Natalya Ananyeva, PhD, HB/DPPT/OTAT/CBER  
Svetlana Shestopal, PhD, HB/DPPT/OTAT/CBER

**IG Participants:**  
Joan Robertson (Vice President (VP), Regulatory Affairs, Bioscience, Grifols Shared Services, NA)  
Sebastian Gascon (VP, Quality, Regulatory Compliance & Technical Director, Instituto Grifols, S.A.)  
Salvador Grancha (VP, Research and Development, Instituto Grifols, S.A.)  
Sonia Amoros (Director, Global Regulatory Affairs, Grifols, S.A.)

**Amendment(s):** 3

### **Summary of Discussion**

FDA emphasized that in-support testing is a critical component of the original BLA review process and stated it is CBER's common practice to test at least three Drug Product (DP) lots. FDA further stated that the validation DP lots described in the BLA are not suitable for in-support testing because they have exceeded the shelf-life period. FDA acknowledged receipt of Amendment 3, dated December 2, 2016, with information regarding post-validation batch IBND6L3MP1 and asked the applicant if it has any more recently manufactured DP lots available for CBER's in-support testing, which are still within the 24-month shelf life.

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IG stated that IBND6L3MP1 is the only DP lot available at this time to provide to the Agency for in-support testing.

FDA then asked the applicant if it would be feasible to manufacture two additional DP lots for CBER's in-support testing to be performed within the BLA review cycle. Additionally, FDA asked to specify the time frame within which to manufacture these additional lots from start to the final release testing.

IG stated that it will be able to manufacture these additional lots and have them available to CBER for in-support testing sometime in March of 2017. It takes about a total of (b) (4) to manufacture these DP lots from start to the final release testing.

FDA asked IG how the samples are configured for the final release testing, specifically: whether the release testing is conducted before or after pre-filling the syringes; how the samples are handled (if they represent the assembled system) for testing individual components; and how many samples are tested for final product release according to the firm's Sampling Plan.

IG stated that this would depend on the fill size and operational objectives.

FDA informed the applicant that the questions raised during this teleconference will be communicated formally via Information Request. FDA also mentioned that pre-license inspection is planned for the applicant's facility in Barcelona, Spain and stated that more information will be provided by the DMPQ reviewer in due time.

IG acknowledged and expressed willingness to cooperate and provide response in a timely manner.

*Signature:* \_\_\_\_\_

Drafted: Yu Do/December 12, 2016

Revised: Yu Do/December 17, 2016

Revised: Natalya Ananyeva/December 17 & 19, 2016

Reviewed: Svetlana Shestopal/December 19, 2016