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29 September 2015
Dr. Tomas Salmonson
European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
London E14 5EU
E14 4HB United Kingdom

[redacted]

Subject: Withdrawal of VeraSeal (Human Fibrinogen / Human Thrombin) solutions for sealant - EMA Procedure no. EMEA/H/C/003914

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, Instituto Grifols, S.A. has taken the decision to withdraw the application for Marketing Authorisation of VeraSeal (Human Fibrinogen / Human Thrombin) solutions for sealant, which was intended to be used for supportive treatment where standard surgical techniques are insufficient, for improvement of haemostasis in vascular surgery and as a suture support in vascular surgery

This withdrawal is based on the following reason:

- Additional data are required to address questions raised during the assessment process (LoOI) of this application. Additional data from three on-going clinical trials are required in order to address the CHMP questions. These data will not be available within the timeframe allowed for this procedure.

It is the applicant's intention to evaluate a new submission when the three on-going clinical trials have finished.

There are no compassionate use programmes. Accordingly there are no consequences of the withdrawal.

We reserve the right to make future submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely,

[redacted]