GRIFOLS

Grifols obtains FDA licence for new filling area at its plasma products plant in the USA.

- **The new facilities ensure maximum safety for the sterile filling and lyophilization of Grifols coagulation factors.**

- **The fact that the licence was awarded within 4 months reflects the company's experience and reputation in regulatory affairs with the FDA.**

Barcelona, 7 May 2008: Grifols, the Spanish holding company specialized in the hospital-pharmaceuticals sector, has obtained approval from the *Food and Drug Administration* (FDA) for its new sterile filling area for coagulation factors, at its Los Angeles plasma products plant.

The area is located in new purpose-built facilities, which have been designed to ensure maximum safety in the aseptic filling, sterilization and lyophilization stages of the Grifols coagulation factors (plasma products): Factor VIII, Factor IX and Profilnine. The area is expected to start operating during the second half of the year.

Validation by the US health authorities is the final stage of one of the first investments planned by the group for its Los Angeles plant where, since the purchase of the plant from Mitsubishi Pharma Corp. in 2003, the main goals have been to gradually update and adapt the productive processes to the standards in place at the Barcelona plasma products plant.

This approval was achieved in just 4 months, confirming the company's experience and *know-how* in regulatory affairs with official bodies, both in the United States (FDA) and in Europe (EMEA). It also represents recognition both of GSF sterile filling technology, [1] patented by Grifols, and of *Grifols Engineering*, which was responsible for designing the entire project.

[1] Grifols Sterile Filling

The building will also house a dedicated line for the sterile filling of albumin (plasma product). These facilities are currently at the second stage of project execution, and the company expects to obtain FDA approval for them at the start of 2009.

Because the hemoderivatives production process involves biological products, aseptic filling and sterilization are one of the most critical stages. Grifols' constant technological innovation, through Grifols Engineering, to improve its productive processes, means the company has one of the safest sterile filling systems in the industry, ensuring maximum quality standards. However, this improvement will not have a significant impact on margins.

About Grifols

Grifols is a Spanish holding company specialized in the pharmaceutical-hospital sector and is present in more than 90 countries. Since 2006, the company has been listed on the Spanish Continuous Market and forms part of the Ibex-35. Currently it is the first company in the European sector in plasma derivatives and the fourth in production worldwide. In upcoming years, the company will strengthen its leadership in the industry as a vertically integrated company, thanks to recent investments and those which will be carried out in 2008-2012, representing 400 million euros. In terms of raw materials, Grifols has ensured its plasma supply with 77 plasmapheresis centres in the United States and in terms of fractionation, its plants in Barcelona (Spain) and Los Angeles (United States) will allow the company to respond to the growing market demand. Nevertheless, the company is preparing for sustained growth in the following 8-10 years and has launched an ambitious investment plan.