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FDA approves Baxter's new manufacturing unit

19 May 2015 | News | By BioSpectrum Bureau

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Baxter International has announced that the US Food and Drug Administration (US FDA) has approved its supplemental drug application to establish its Sabinanigo facility in Spain, as an approved manufacturing site for 0.9 percent Sodium Chloride injection, USP, for the American market.

The approval includes product presentations in 250 mL, 500 mL and 1000 mL, which Baxter has been distributing in the US to alleviate a drug shortage with the knowledge of the FDA. All three of these product presentations of 0.9 percent Sodium Chloride Injection, USP, more commonly known as saline, have been listed in drug shortage databases maintained by the FDA and the American Society of Health-System Pharmacists over the past two years.

"The approval of an additional manufacturing site for Sodium Chloride Injection in the US gives us greater flexibility to respond to market demand fluctuations and will help as we continue to meet patient and healthcare provider need for this critical product," said Mr Brik Eyre, president of Baxter's Hospital Products business. He added,"FDA was quick to recognize the benefit of addressing industry demand for sterile IV solutions in collaboration with companies like Baxter. This approval illustrates the strength of Baxter's global manufacturing network, as well as our commitment to meeting important healthcare needs."