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BAXTER HEALTHCARE AGREES TO U.S. COURT ORDER TO REMEDY INFUSION PUMP DEFECTS AND TO COMPLY WITH FDA REQUIREMENTS

CHICAGO – A federal judge approved a consent decree today settling a civil lawsuit with Baxter Healthcare Corp. and two of its top executives that the United States filed last fall when the U.S. Food and Drug Administration seized 7,140 intravenous infusion pumps, alleging they were faulty and violated the federal Food, Drug and Cosmetic Act. Under the decree, which permanently enjoins future violations, Baxter and the executives agreed to stop manufacturing and distributing within the United States all models of two types of pumps until Baxter corrects manufacturing deficiencies and brings the devices into compliance with FDA's requirements and regulations, announced Patrick J. Fitzgerald, United States Attorney for the Northern District of Illinois.

The decree was signed today by U.S. District Judge Wayne Andersen in Federal Court in Chicago.

The decree covers two types of pumps manufactured in Singapore by Baxter, which is based in Deerfield, Ill. They are the Colleague Volumetric Infusion Pump and the Syndeo PCA Syringe Pump. Infusion pumps are electronic devices used to administer solutions and medications intravenously to patients.

The FDA and the U.S. Marshal Service seized 7,140 infusion pumps last October from Baxter's facilities in Buffalo Grove, Ill., and from another firm's facilities in Waukegan. At the same time, the government filed its lawsuit to forfeit and condemn the allegedly faulty devices. The suit alleged that the devices were adulterated under federal law because the methods used in, and the facilities and controls used for, their manufacture, packing, storage and installation did not conform with current good manufacturing practice (CGMP) and the Quality System Regulation (QS) for devices.

Baxter and defendants Robert L. Parkinson, its chief executive officer, and Peter J. Arduini, the company's corporate vice president and president of Baxter's Medication Delivery Services, signed the consent decree without admitting the allegations and disclaiming any liability.

During the FDA's most recent inspection of Baxter's Round Lake facility, conducted June 20-30, 2005, design defects relating to the reliability of the infusion pumps were revealed. Baxter initiated a voluntary world-wide hold on all Colleague Infusion Pumps due to a product design defect relating to a temperature sensitive component of the device's timing circuit, which caused some pumps to fail. Baxter also initiated a voluntary world-wide hold on all Syndeo Infusion Pumps due to design defects that could cause the device to stop functioning. This defect resulted from an error in the timing component that occurs over time.

Under the consent decree, Baxter agreed to take all necessary measures to ensure compliance with the CGMP and QS requirements by all of its facilities that manufacture, process, pack, label, hold or distribute the Colleague and Syndeo pumps in the United States. The decree also requires Baxter to retain an independent expert consultant to conduct inspections of its infusion pump facilities and certify to FDA that corrections have been made. FDA will continue to monitor these activities through its inspections.

The FDA will allow Baxter to continue to provide routine service maintenance or to replace components, parts, or accessories for the infusion pumps that were already in possession of customers before October 12, 2005. Baxter is also required to submit to FDA an acceptable detailed corrective action plan to bring the Colleague and Syndeo pumps currently in use in the United States into compliance with federal law. If corrective action under the decree is completed and Baxter has been allowed to resume manufacturing and distribution, the firm must also hire an independent auditor to conduct audit inspections of its infusion pump facilities at least once a year for at least four years. Results of these audit inspections will be reported directly to FDA. If Baxter fails to comply with any provision of the decree, or violates the law or FDA regulations, FDA may order the company to again stop manufacturing and distributing, recall the products or take other action. The decree calls for Baxter to post a $20 million letter of credit with the Court as a bond to assure its compliance.

The government is being represented by Assistant U.S. Attorney Donald Lorenzen.

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