



FDA News

FOR IMMEDIATE RELEASE

P05-70

October 14, 2005

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United States Marshals Seize Violative Infusion Pumps Made by Baxter Healthcare Corporation

At the request of the U.S. Food and Drug Administration (FDA), on October 12, 2005, the U.S. District Court for the Northern District of Illinois issued a warrant for seizure of three types of infusion pumps manufactured by Baxter Healthcare Corporation because FDA inspections revealed that the firm has continually failed to follow medical device manufacturing requirements.

The seized products are: SYNDEO PCA Syringe Pumps, Colleague Volumetric Infusion Pumps, and Colleague CX Volumetric Infusion Pumps. Baxter has distributed these products worldwide. Infusion pumps are electronic devices intended to control delivery of solutions and medications to patients. Pump shutdown could result in serious injuries or death to critically ill patients who depend on continuous infusion medications and/or life-sustaining medications.

"This case demonstrates that the FDA will take the necessary steps to protect America's public health," said Margaret O'K. Glavin, FDA Associate Commissioner for Regulatory Affairs. "Today's notification shows our commitment to informing the public about important safety issues."

Four thousand SYNDEO and Colleague infusion pumps were seized by the U.S. Marshals Service from Baxter's warehouse in Buffalo Grove, Ill., and 135 SYNDEO pumps from a distributor's warehouse in Waukegan, Ill. No products were seized from healthcare facilities or individual users, and there are no plans to do so. Healthcare facilities can continue to use pumps in their possession, guided by instructions Baxter provided previously, but should recognize the types of problems that could occur and have a backup plan in place, especially in situations where the pump is part of a life-saving function. More detailed recommendations for users of specific pump models are available on Baxter's web site at www.Baxter.com.

Baxter was previously issued Warning Letters outlining the violations and was given an opportunity to correct the violations, but failed to take appropriate actions. On February 25, March 15, July 6, and July 20, 2005, Baxter notified the public of the potential health hazard associated with these products.

FDA alleges that none of the seized infusion pumps were manufactured under the proper controls and that the Colleague pumps have a design defect that may cause the pumps to stop and shut down during infusion therapy. Further, FDA believes Baxter failed to inform FDA of the Colleague infusion pump failures, in violation of the Medical Device Reporting regulation of the Federal Food, Drug and Cosmetic Act (FD&C Act).

FDA believes that the seizure will help ensure that pumps in the warehouses are not distributed until the problems are corrected and they can be safely used.

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