U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

News & Events

FDA NEWS RELEASE

For Immediate Release: May 3, 2010
Media Inquiries: Dick Thompson, 240-753-3049, dick.thompson@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Issues Statement on Baxter's Recall of Colleague Infusion Pumps

The U.S. Food and Drug Administration sent a letter to Baxter Healthcare Corp. on April 30 ordering the company to recall and destroy all of its Colleague Volumetric Infusion Pumps (Colleague pumps) currently in use in the United States. This action is based on a longstanding failure to correct many serious problems with the pumps. The FDA believes there may be as many as 200,000 of those pumps currently in use.

Additionally, the FDA is ordering the company to provide refunds to customers or replace pumps at no cost to customers help defray the cost of replacement.

Infusion pumps are devices that deliver fluids, including nutrients and medications, into a patient's body in a controlled manner. They are widely used in hospitals, other clinical settings and, increasingly, in the home because they allow a greater level of accuracy in fluid delivery.

Hospitals and other users of Baxter's Colleague pumps will be receiving further instruction and information from Baxter and the FDA regarding their transition.

The FDA has been working with Baxter since 1999 to correct numerous device flaws. Since then, Colleague pumps have been the subject of several Class I recalls for battery swelling, inadvertent power off, service data errors, and other issues.
In June 2006, the FDA was obtained a consent decree of permanent injunction in which Baxter agreed to stop manufacturing and distributing all models of the Colleague pump until the company corrected manufacturing deficiencies and until devices in use were brought into compliance. Since then, Baxter has made numerous changes to the Colleague pumps but these changes have not corrected the product defect leading to the permanent injunction.

On April 8, 2010, Baxter submitted a proposed correction schedule to the FDA that stated that Baxter did not plan to begin the latest round of corrections to the adulterated and misbranded pumps until May 2012. The proposal also stated that Baxter does not anticipate completion of the proposed corrections until 2013. On that schedule, a device with known safety concerns would remain in use on patients needing specialized care until 2013. FDA found this proposal unacceptable. The 2006 consent decree gave FDA authority to take any action it deemed appropriate. The FDA has determined that this action is necessary, as Baxter has failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague infusion pumps still in use.

Therefore the FDA is now ordering Baxter to:

- Recall and destroy all Colleague infusion pumps.
- Reimburse customers for the value of the recalled device
- Assist in finding a replacement for these customers.

Infusion pumps, including the Baxter Colleague models, have been the source of persistent safety problems. In the past five years, the FDA has received more than 56,000 reports of adverse events associated with the use of infusion pumps. Those events have included serious injuries and more than 500 deaths. Between 2005 and 2009, 87 infusion pump recalls were conducted to address identified safety concerns, according to FDA data.

An FDA analysis of these adverse events has uncovered software defects, user interface problems and mechanical and electrical failures. Problems with infusion pumps are not confined to one manufacturer or one type of device.
In response, last month the FDA announced a new initiative to address safety problems associated with infusion pumps. As part of its initiative, the FDA is moving to establish additional premarket requirements manufacturers will be expected to meet, in part through static testing in FDA's facilities before device submissions. The FDA is also holding a May public workshop on infusion pump design, and the agency is raising public awareness of the issue among health care workers and patients.

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Safety

Baxter Colleague Infusion Pumps: FDA Ordering Recall

Audience: Hospital Risk Managers

[Posted 05/04/2010] FDA notified healthcare professionals and consumers that it has ordered Baxter to recall and destroy all of its Colleague Volumetric Infusion Pumps (Colleague pumps) currently in use. This action is based on a longstanding failure to correct many serious problems with the pumps. The FDA believes there may be as many as 200,000 of those pumps currently in use. FDA is ordering Baxter to recall and destroy all Colleague infusion pumps, reimburse customers for the value of the recalled device, and assist in finding a replacement for these customers. Hospitals and other users of Baxter's Colleague pumps will be receiving further instruction and information from Baxter and the FDA regarding their transition.

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