DEERFIELD, Ill., May 15, 2009 – Today, Baxter is announcing that its investigation of reports from Beebe Medical Center has determined that the three patient events are unrelated to product quality involving the company’s heparin premix products.

The company and the U.S. Food and Drug Administration (FDA) launched a comprehensive investigation after being contacted on Friday, May 8, 2009 by Beebe Medical Center in Lewes, DE regarding adverse events involving three patients who experienced intracranial bleeding, a serious and life-threatening issue.

Baxter worked with the hospital and FDA to rapidly collect information to assess the patient events and the hospital’s use of the company’s premix product.

“Following extensive product testing and further medical evaluation, we are confident that the events at Beebe Medical Center are unfortunate, isolated, institution-specific issues, unrelated to the quality of Baxter’s heparin premix product,” said Camille Farhat, general manager of Baxter Pharmaceuticals & Technologies, part of Baxter’s Medication Delivery business. “Our thoughts are with the patients and families involved in these tragic events.”

Baxter’s investigation included conducting an array of forensic and analytical tests to verify the product’s integrity, such as purity and potency testing, and to confirm that contaminants were not present. The supply chain, including raw materials, was examined and found to meet all requirements. All tests on samples obtained from the hospital, retained samples from the same lot, and samples produced before and after the lot in question confirmed that the product’s formulation was within specifications and met all requirements.

Baxter’s medical investigation involved flying a team of physicians, pharmacists and nurses to Beebe Medical Center within 24 hours of notification to gather information about the sequence of events, patient conditions, other drugs and medical devices in use at the time, and to request additional medical information necessary to understand how three patients presented with intracranial bleeding.

Evaluation of the medical information received indicated that the product performed as expected and that the intracranial bleeding was related to underlying medical conditions and risk factors that increase the relative risks involved in using a particular drug.

Based on the findings from Baxter’s investigation, as well as FDA’s, Baxter is confirming that the unfortunate patient events which occurred at Beebe Medical Center were isolated, institution-specific issues and this critical product continues to be safe and effective to use.

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