



Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Baxter Issues Urgent Nationwide Voluntary Recall of Heparin 1,000 Units/ml 10 and 30ml Multi-Dose Vials

NDC NUMBERS 0641-2440-45, 0641-2440-41, 0641-2450-45 and 0641-2450-41; LOTS: 107054, 117085, 047056, 097081, 107024, 107064, 107066, 107074, 107111

Media Contacts:

Erin Gardiner, (847) 948-4210

Christopher King, (847) 948-4274

FOR IMMEDIATE RELEASE -- DEERFIELD, Ill., January 25, 2008 – Baxter Healthcare Corporation has announced the voluntary recall of nine lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials. The company began recalling the lots on January 17, 2008 as a precautionary measure due to an increase in the number of reports of adverse patient reactions that may be associated with the product. Baxter is conducting a thorough investigation of these reports to identify the cause of the increase in allergic-type reactions.

Adverse patient reactions have included: stomach pain or discomfort, nausea, vomiting, diarrhea, decreased or low blood pressure, chest pain, fast heart rate, dizziness, fainting, unresponsiveness, shortness of breath, feeling your heart beat strong or fast, drug ineffectiveness, burning sensation, redness or paleness of skin, abnormal sensation of the skin, mouth or lips, flushing, increased sweating, decreased skin sensitivity, headache, feeling unwell, restlessness, watery eyes, throat swelling, thirst and difficulty opening the mouth. Some of these reactions may be severe or life threatening.

Heparin is a prescription, injectable blood anticoagulant (also called a blood thinner). The 1,000 units/mL multi-dose vials are primarily used for hemodialysis and cardiac invasive procedures. To date, the company has not observed a significant increase in adverse event reports occurring with any other of its heparin presentations.

Customers have been instructed to discontinue use and segregate the recalled product from the rest of their inventory. Customers should then contact Baxter to arrange for return and replacement product. Customers with recalled product purchased indirectly should contact their wholesaler or distributor for return and replacement product. Customers with questions may contact Baxter at 1-800-667-0959. Representatives are available Monday through Friday from 7 a.m. to 6 p.m. CT.

Baxter International Inc. through its subsidiaries, assists healthcare professionals and their patients with the treatment of complex medical conditions, including cancer, hemophilia, immune disorders, kidney disease and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives. For more information about Baxter, visit www.baxter.com.

#

[RSS Feed for FDA Recalls Information](#) [\[what's this?\]](#)

 [Sign up for Recall email updates.](#)

[FDA Newsroom](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

[FDA Website Management Staff](#)