

FDA Investigating McNeil Consumer Healthcare After Product Recalls

Prompted by McNeil Consumer Healthcare's most recent recall of its children's and infants' liquid pain-relief products, the FDA is conducting an investigation to determine if there are similar problems throughout McNeil's drug manufacturing practices. On April 30, 2010, McNeil announced it was recalling all unexpired lots of certain brand-name over-the-counter children's and infants' liquid medications—including more than 40 variations of Tylenol, Motrin, Zyrtec, and Benadryl products—because of manufacturing deficiencies that could affect quality, purity, or potency. The most recent incident marks the second time this year, and the third time in less than nine months, that McNeil has recalled children's and infants' liquid pain-relief products. In a May 1, 2010, news release, the FDA said that some of the recalled products may contain higher concentrations of active ingredients than specified, whereas others may contain foreign particles or inactive ingredients that may not meet internal testing requirements. McNeil subsequently closed the Fort Washington, Pa., facility where the recalled products were made and said it would not reopen that plant without notifying the FDA. For more information, visit <http://www.aafp.org/news-now/health-of-the-public/20100518fdaandmcneil.html> and <http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM212243.pdf>.

***MED WATCH* McNeil Recalls Pediatric Products; Infusion Pumps Also Recalled**

McNeil Consumer Healthcare said in an April 30, 2010, news release that it is recalling all lots of certain brand-name, over-the-counter children's and infants' liquid medications, including more than 40 variations of Tylenol, Motrin, Zyrtec, and Benadryl products. McNeil said the products were being recalled because of manufacturing deficiencies that could affect quality, purity, or potency. In a May 1, 2010, news release, U.S. Food and Drug Administration (FDA) officials said that some of the recalled products may contain higher concentrations of active ingredients than specified, whereas others contain foreign particles or inactive ingredients that may not meet internal testing requirements. The FDA said generic versions of the products are not affected by the recall and are considered safe to use. In another recall, The FDA has ordered Baxter Healthcare Corp. to recall and destroy all of its Colleague Volumetric Infusion Pumps. In addition, Baxter must reimburse customers for the value of the recalled pumps and assist them in finding replacement devices. The FDA estimates that there are as many as 200,000 Colleague pumps currently in use. Colleague pumps have been the subject of Class I recalls—the FDA's most severe recall status, signifying there is a potential for serious injury or death associated with a product—because of battery swelling, inadvertent power loss, service data errors, and other issues. For more information, visit <http://www.aafp.org/news-now/health-of-the-public/20100504mcneil--recall.html>, <http://www.fda.gov/Safety/Recalls/ucm210443.htm>,

<http://www.aafp.org/news-now/health-of-the-public/20100505baxter-recall.html>, and
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210664.htm>.