



## PRODUCT RECALL INFORMATION

Information about the recall of certain Infants' and Children's products April 30, 2010

### **McNeil Consumer Healthcare Announces Voluntary Recall of Certain OTC Infants' and Children's Products**

Information about previous recalls

Fort Washington, PA (April 30, 2010) – McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., in consultation with the U.S. Food and Drug Administration (FDA), is voluntarily recalling all lots that have not yet expired of certain over-the-counter (OTC) Children's and Infants' liquid products manufactured in the United States and distributed in the United States, Canada, Dominican Republic, Dubai (UAE), Fiji, Guam, Guatemala, Jamaica, Puerto Rico, Panama, Trinidad & Tobago, and Kuwait. (SEE RECALLED PRODUCT LIST BELOW).

McNeil Consumer Healthcare is initiating this voluntary recall because some of these products may not meet required quality standards. This recall is not being undertaken on the basis of adverse medical events. However, as a precautionary measure, parents and caregivers should not administer these products to their children. Some of the products included in the recall may contain a higher concentration of active ingredient than is specified; others may contain inactive ingredients that may not meet internal testing requirements; and others may contain tiny particles. While the potential for serious medical events is remote, the company advises consumers who have purchased these recalled products to discontinue use.

The company is conducting a comprehensive quality assessment across its manufacturing operations and has identified corrective actions that will be implemented before new manufacturing is initiated at the plant where the recalled products were made.

Consumers can contact the company at 1-888-222-6036 and also at [www.mcneilproductrecall.com](http://www.mcneilproductrecall.com). Parents and caregivers who are not sure about alternative pediatric health treatment options should talk to their doctor or pharmacist and are reminded to never give drug products to infants and children that are not intended for those age groups as this could result in serious harm.

For additional information, including affected NDC numbers, consumers should visit our website [www.mcneilproductrecall.com](http://www.mcneilproductrecall.com) or call 1-888-222-6036 (Monday-Friday 8 a.m. to 10 p.m. Eastern Time, and Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time). Any adverse reactions may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

McNeil Consumer Healthcare, Division of McNeil-PPC, Inc. markets a broad range of well-known OTC products.