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

Fort Washington, PA (April 30th, 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. 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 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.

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

Note: Product NDC numbers can be located on the label of the bottle above the brand name

PRODUCTS	NDC Number
TYLENOL® INFANTS' DROPS	
CONCENTRATED TYLENOL® INFANTS' DROPS 1 OZ. GRAPE FLAVOR	50580-144-01
CONCENTRATED TYLENOL® INFANTS' DROPS 0.5 OZ. GRAPE FLAVOR*	50580-144-15
CONCENTRATED TYLENOL® INFANTS' DROPS 1 OZ. CHERRY DYE FREE	50580-167-01
CONCENTRATED TYLENOL® INFANTS' DROPS 0.5 OZ. CHERRY FLAVOR	50580-143-15
CONCENTRATED TYLENOL® INFANTS' DROPS 1 OZ. CHERRY FLAVOR	50580-143-30
CONCENTRATED TYLENOL® INFANTS' DROPS 0.5 OZ. GRAPE - HOSPITAL	50580-144-18
CONCENTRATED TYLENOL® INFANTS' DROPS 0.25 OZ. GRAPE - SAMPLE	50580-144-40
CHILDREN'S TYLENOL® SUSPENSIONS	
CHILDREN'S TYLENOL® SUSPENSION 2 OZ. CHERRY BLAST FLAVOR	50580-123-02
CHILDREN'S TYLENOL® SUSPENSION 4 OZ. CHERRY BLAST FLAVOR	50580-123-04
CHILDREN'S TYLENOL® DYE-FREE SUSPENSION 4 OZ. CHERRY FLAVOR	50580-166-04
CHILDREN'S TYLENOL® SUSPENSION 4 OZ. GRAPE SPLASH	50580-296-04
CHILDREN'S TYLENOL® SUSPENSION 4 OZ. BUBBLEGUM FLAVOR	50580-407-04
CHILDREN'S TYLENOL® SUSPENSION 4 OZ. VERY BERRY STRAWBERRY FLAVOR	50580-493-04
CHILDREN'S TYLENOL® SUSPENSION 1 OZ. CHERRY BLAST FLAVOR – SAMPLE	50580-123-01

CHILDREN’S TYLENOL® SUSPENSION 4 OZ. CHERRY BLAST FLAVOR – HOSPITAL	50580-123-03
CHILDREN’S TYLENOL® PLUS SUSPENSIONS	
CHILDREN’S TYLENOL® PLUS SUSPENSION 4 OZ. COUGH & SORE THROAT CHERRY FLAVOR	50580-247-04
CHILDREN’S TYLENOL® PLUS SUSPENSION 4 OZ. COUGH & RUNNY NOSE CHERRY FLAVOR	50580-249-04
CHILDREN’S TYLENOL® PLUS DYE-FREE SUSPENSION 4 OZ. COLD & STUFFY NOSE GRAPE FLAVOR	50580-253-04
CHILDREN’S TYLENOL® PLUS DYE-FREE SUSPENSION 4 OZ. COLD & COUGH GRAPE FLAVOR	50580-254-04
CHILDREN’S TYLENOL® PLUS DYE-FREE SUSPENSION 4 OZ. MULTI-SYMPTOM COLD GRAPE FLAVOR	50580-255-04
CHILDREN’S TYLENOL® PLUS SUSPENSION 4 OZ. FLU BUBBLEGUM FLAVOR	50580-386-04
CHILDREN’S TYLENOL® PLUS SUSPENSION 4 OZ. COLD GRAPE FLAVOR	50580-387-04
CHILDREN’S TYLENOL® PLUS SUSPENSION 4 OZ. COLD & ALLERGY BUBBLEGUM FLAVOR	50580-390-04
CHILDREN’S TYLENOL® PLUS SUSPENSION 4 OZ. MULTI-SYMPTOM COLD GRAPE FLAVOR	50580-391-04
MOTRIN® INFANTS’ DROPS	
CONCENTRATED MOTRIN® INFANTS’ DROPS 1 OZ. BERRY DYE FREE	50580-198-01
CONCENTRATED MOTRIN® INFANTS’ DROPS 0.5 OZ. BERRY DYE FREE	50580-198-15
CONCENTRATED MOTRIN® INFANTS’ DROPS 0.5 OZ. BERRY FLAVOR*	50580-100-15
CHILDREN’S MOTRIN® SUSPENSIONS	
CHILDREN’S MOTRIN® SUSPENSION 4 OZ. BERRY DYE FREE	50580-184-04
CHILDREN’S MOTRIN® SUSPENSION 2 OZ. BERRY FLAVOR	50580-601-02
CHILDREN’S MOTRIN® SUSPENSION 4 OZ. BERRY FLAVOR	50580-601-04
CHILDREN’S MOTRIN® SUSPENSION 4 OZ. TROPICAL PUNCH FLAVOR	50580-215-04
CHILDREN’S MOTRIN® SUSPENSION 4 OZ. GRAPE FLAVOR	50580-603-04
CHILDREN’S MOTRIN® SUSPENSION 4 OZ. BUBBLEGUM FLAVOR	50580-604-04
CHILDREN’S MOTRIN® SUSPENSION 1 OZ. GRAPE SAMPLE	50580-603-01
CHILDREN’S MOTRIN® SUSPENSION 1 OZ. BUBBLEGUM SAMPLE	50580-604-01
CHILDREN’S MOTRIN® SUSPENSION 1 OZ. BERRY SAMPLE	50580-601-01
CHILDREN’S MOTRIN® SUSPENSION 4 OZ. BERRY HOSPITAL	50580-601-50
CHILDREN’S MOTRIN® SUSPENSION 4 OZ. COLD BERRY FLAVOR	50580-902-04
CHILDREN’S ZYRTEC® LIQUIDS IN BOTTLES	
CHILDREN’S ZYRTEC® 4 OZ. BUBBLEGUM SYRUP	50580-721-04
CHILDREN’S ZYRTEC® DYE FREE 4 OZ. GRAPE SYRUP	50580-730-04
CHILDREN’S ZYRTEC® SUGAR-FREE DYE-FREE 0.5 OZ. GRAPE	50580-730-15
CHILDREN’S ZYRTEC® SUGAR-FREE DYE-FREE 0.5 OZ. BUBBLEGUM	50580-721-15
CHILDREN’S ZYRTEC® SUGAR-FREE DYE-FREE 2 X 4 OZ. BUBBLEGUM LIQUID	50580-721-08
CHILDREN'S BENADRYL® ALLERGY LIQUIDS IN BOTTLES	
CHILDREN'S BENADRYL® ALLERGY 4 OZ. BUBBLEGUM FLAVORED LIQUID	50580-535-04

* CONCENTRATED TYLENOL® INFANTS' DROPS 0.5 OZ. GRAPE FLAVOR is also included in JOHNSON'S ® Baby Relief Kit.

* CONCENTRATED MOTRIN® INFANTS' DROPS 0.5 OZ. BERRY FLAVOR is also included in JOHNSON'S ® Baby Relief Kit.