Recall of Liquid Products for Children:
What Consumers Need to Know

The Food and Drug Administration (FDA) wants consumers to stop using liquid infant’s and children’s products that are part of a voluntary recall announced on April 30, 2010.

The firm McNeil Consumer Healthcare has recalled certain infant’s and children’s liquid products due to manufacturing deficiencies which may affect quality, purity, or potency.

FDA, which enforces laws and regulations designed to protect patients and consumers, is closely monitoring this recall of liquid products for infants and children.

“We want to be certain that consumers discontinue using these products and that they know what to do if they have concerns about a specific product,” says Commissioner of Food and Drugs Margaret A. Hamburg, M.D. “While the potential for serious health problems is remote, Americans deserve medications that are safe, effective, and of the highest quality. We are investi-

Read labels carefully to know whether the liquid product for infants or children you are considering is among those that were voluntarily recalled. A list of these products is available on McNeil Consumer Healthcare’s recall notice, online at www.mcneilproductrecall.com/page.jhtml?id=/include/new_recall.inc
gating the products and facilities associated with this recall and will provide updates as we learn more."

**What products are affected by this recall?**
The products include certain liquid infant’s and children’s products sold under the brand names
- Tylenol
- Motrin
- Zyrtec
- Benadryl

A complete list of recalled products is posted with McNeil’s recall notice, which is available online at: www.mcneilproductrecall.com/page.jhtml?id=/include/new_recall.inc

**Why were these products recalled?**
Some of these products may not meet required quality standards. Some of the recalled products may contain a higher concentration of active ingredient than specified. Others contain inactive ingredients that may not meet internal testing requirements. And others may contain tiny particles.

**What is the advice for parents, caregivers, and other consumers?**
Stop using these products. Do not administer them to infants and children. For further instructions, see McNeil’s Web site at: www.mcneilproductrecall.com

**What can I use instead of the recalled products?**
There are a number of other products on the market, including generic versions of the recalled products, that are not affected by the recall and that are intended for use in infants and children. FDA does not anticipate that there will be a shortage of alternative products.

The agency recommends that you check the labeling of these products. Discuss any questions you may have with your pharmacist or other health care professional.

**Can I give my child adult strength Tylenol or Motrin products that are not being recalled?**
No. Consumers should not give drug products to infants and children that are not intended for those age groups. For example, do not give adult-strength products to children, and do not give children’s strength products to infants. Doing so can result in serious harm.

**I gave my child some of the recalled medication. What do I do? Is my child at risk?**
According to the information FDA has at this time, the potential for serious medical problems is remote. If your child shows any unexpected symptoms after use of any of the recalled products, contact your health care professional.

**If I think my child may be having a side effect from one of the products involved in this recall, whom should I notify?**
Consumers and health care professionals can report adverse reactions or quality problems experienced with the use of these products to FDA’s MedWatch Adverse Event Reporting Program either online, by regular mail, by fax, or by phone.
- Online at www.fda.gov/medwatch
- Regular Mail sent to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178
- Phone: 1-800-332-1088

**How can I get my money back on recalled products I have purchased?**
McNeil has posted instructions to help you get a refund or a coupon for a replacement at: www.mcneilproductrecall.com/page.jhtml?id=/include/faq.inc

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

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