U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

News & Events

FDA NEWS RELEASE

For Immediate Release: May 1, 2010
Media Inquiries: Elaine Ganz Bobo, 240.620.6896, Elaine.Bobo@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA provides consumer advice following recall of products for infants and children

Working in consultation with the United States Food and Drug Administration (FDA), McNeil Consumer Healthcare is implementing a voluntary recall of infant and children's liquid products due to manufacturing deficiencies which may affect quality, purity or potency. Following McNeil's recall announcement on Friday evening, the FDA is providing additional advice to consumers.

"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," said 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 investigating 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 Tylenol®, Motrin®, Zyrtec®, and Benadryl® products. For a complete list of recalled products, please see the recall notice[1].

Why were these products recalled?
McNeil Consumer Healthcare is initiating this voluntary recall because some of these products may not meet required quality standards. 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 specified; others 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, FDA advises consumers who have purchased these recalled products to discontinue use.

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, which are intended for use in infants and children and are not affected by the recall. FDA recommends that you check the labeling of these products. If you have any questions, you should discuss this with your pharmacist or other health care professional. FDA does not anticipate that there will be a shortage of alternative products.

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. This could result in serious harm.

What should I do if I have some of the medication at home?
FDA recommends that consumers stop using these products.
For further instructions, see McNeil's website at: www.mcneilproductrecall.com[2]

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

If I think my child may be having an adverse reaction to one of the products involved in this recall, who should I notify?
Adverse reactions or quality problems experienced with the use of these products may be reported to FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax, using the contact information at the bottom of this sheet. The agency asks health care professionals and consumers to report

any adverse reactions 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 [3].

Related information:

Facts about Current Good Manufacturing Practices (CGMPs) [4]

Links on this page:

1. http://www.mcneilproductrecall.com/page.jhtml?id=/include/new_recall.inc
2. http://www.mcneilproductrecall.com/
3. http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
4. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm