

MEDIA UPDATE

On April 30, 2010, McNeil Consumer Healthcare implemented a voluntary recall of its infant's and children's liquid drug products due to manufacturing deficiencies, which may have affected the quality, purity, or potency of the drugs. The products included certain liquid infant's and children's Tylenol, Motrin, Zyrtec, and Benadryl products. A complete list of recalled products is available on McNeil's Web site. A Web link to this list can be found on the FDA's Web site.

McNeil is responsible for implementing the recall to ensure these products are removed from retail shelves. FDA has advised consumers who purchased recalled products to discontinue use as a precautionary measure. FDA believes that the chance of serious adverse health consequences is remote.

Other products are available that can be substituted for the recalled products. When seeking alternatives to the recalled products, and in all situations, consumers should not give any products to infants and children that are not intended for those age groups. Doing so could result in serious harm.

FDA is actively pursuing issues related to this recall. FDA has been in regular contact with McNeil about the company's recall activities. While FDA does not have authority to order recalls of drugs, FDA does monitor recalls as they proceed, and the agency will continue to work to ensure that the manufacturer and other companies in the distribution chain stop selling the recalled products.

In addition to questions about the recall, FDA has received a large number of inquiries about how the manufacturing deficiencies found at McNeil may have impacted the quality and safety of their infant's and children's liquid products. McNeil has shut down all manufacturing at the Fort Washington, Pa., plant where the recalled products were made and has said it will not resume manufacturing at that facility without notifying the FDA.

Drug safety analysts and other medical professionals at FDA have begun a comprehensive review of complaints received by the agency to determine the significance of any adverse events reported and any connection to the use of the recalled products. The FDA is conducting a company-wide investigation of McNeil Consumer Healthcare's drug manufacturing practices to determine whether similar problems exist throughout the company and what additional steps the agency must take to ensure that these problems do not recur.

As a public health agency, FDA seeks to prevent harm to the American public. Drug manufacturers, with FDA oversight, are responsible for ensuring the safety, effectiveness, and quality of their products. McNeil's current recall, involving products for children and infants in millions of homes, brings the importance around the safety and quality of drugs into focus. Parents and caregivers understandably feel a special concern about the quality of such products. The agency shares their concern and will continue to work to ensure that children will not be exposed to products that may be unsafe.