

FDA Investigating Recall Of Children's Medicine

By Randy Key

Published: May 3, 2010

WASHINGTON (AP) - The Food and Drug Administration said Saturday it was investigating a health-care company for possible other problems following its recall of more than 40 over-the-counter infant's and children's liquid medications.

McNeil Consumer Healthcare, based in Fort Washington, Pa., issued the voluntary recall late Friday in the United States and 11 other countries after consulting with the FDA. The recall involves children's versions of Tylenol, Tylenol Plus, Motrin, Zyrtec and Benadryl, because they don't meet quality standards.

The FDA said it was reviewing procedures at McNeil, which appears to be the sole source of the problems. "We are following through with the facility to make certain that everything has been checked," said FDA spokeswoman Elaine Gansz Bobo.

According to McNeil and the FDA, some of the products recalled may have a higher concentration of active ingredient than is specified on the bottle. Others may contain particles, while still others may contain inactive ingredients that do not meet internal testing requirements.

The FDA called the potential for serious medical problems "remote," but it advised consumers to stop using the medicine as a precaution. It said a health care professional should be consulted if a child has recently taken any of the recalled products and is exhibiting unexpected symptoms.

The FDA also says parents in the interim should consider substitute child medications, such as generic versions. It does not recommend that children be given adult-strength Tylenol or Motrin because they are not intended for younger age groups.

The medicines were made and distributed in the United States, and exported to Canada, the Dominican Republic, Dubai, Fiji, Guam, Guatemala, Jamaica, Puerto Rico, Panama, Trinidad and Tobago and Kuwait.

Children's Tylenol Recall Result of 'Abundance of Caution': FDA

Recall Is Latest of Several for Tylenol Maker in Past Year

By DAN CHILDS
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May 4, 2010—

An "abundance of caution" led to last week's product recall by Tylenol maker McNeil Consumer Healthcare, a U.S. Food and Drug Administration spokeswoman said. But drug safety experts said that serious or not, the episode proves that not just generic drugs can fall victim to quality control problems.

"This recall provides compelling evidence that quality assurance is an issue for all drugmakers, and is not specific to generic products, as many have implied," said Dr. Jerry Avorn, professor of Medicine at Harvard Medical School and chief of the Division of Pharmacoepidemiology and Pharmacoeconomics Brigham and Women's Hospital.

"This shows that the problem isn't generic versus brand, but good manufacturing practices versus sloppy manufacturing practices," said Merrill Goozner, a freelance writer and independent consultant to consumer groups. "The FDA needs more money to police the entire drug manufacturing supply chain, brand name and generic, over-the-counter or prescription."

The company and the FDA issued the voluntary recall of certain over-the-counter (OTC) children's and infants' liquid products after consumer complaints of "tiny particles" in the medicines, as well as the possibility that some of the medications "may contain a higher concentration of active ingredient than is specified" and "others may contain inactive ingredients that may not meet internal testing requirements," according to a press release on the company's Web site.

The recall affects a total of 44 different products sold under the brand names of Tylenol, Motrin, Zyrtec and Benadryl.

Thus far, there is no indication as to which medications of those recalled are linked to each of the problems cited in the company's press release.

Recalled Medicines Pose Little Threat, FDA Says

Elaine Gansz Bobo, a spokeswoman for the FDA, said that at this time, the agency believes the affected medications pose little threat.

"With some recalls, every bit of information is present before the recall," Bobo said. "But this product, because it is widely used and is used in a vulnerable population, it is better to get the information out there... This is not an imminent public health risk."

"The important thing for consumers to understand is that there are no adverse events related to it," said Bonnie Jacobs, spokeswoman for McNeil Consumer Healthcare.

Still, the recall is the drugmaker's third in a year due to quality problems. In December, certain arthritis medications and other products were pulled from the market after reports of an "unusual moldy, musty, or mildew-like odor" and cases of gastrointestinal illness linked to the consumption of these products.

Last September, a number of pediatric liquid products were recalled due to concerns over the quality of an inactive ingredient that is a component of these drugs.

"Speaking as a parent and a pharmacologist, the frequency of these recalls does not foster great confidence in the manufacturing standards for these medicines in that they are being released before quality testing is completed," said Dr. David Kroll, professor of Pharmaceutical Sciences at North Carolina Central University in Durham. "I was struck in particular by the comment from the FDA that parents consider substituting generic versions of the child medicines, rather than use adult strength medicines."

Another potential problem is that the recall affects the same category of medications that came under fire from an FDA advisory committee in 2007.

"The FDA non-prescription drug advisory committee [at the time] found that there was little to no compelling evidence that cough and cold medications are efficacious in children under 6, and they may pose a meaningful risk," said Dr. William Shrank of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital and member of the FDA OTC drug advisory panel.

More Information on Recall Forthcoming

Though Jacobs refused to say why the information linking specific problems to specific drugs had not yet been released, Bobo said the FDA hopes to release the report making those links as early as today.

"What parents need to do is not have a heart attack over it," Bobo said. "If they have already given it to their child, they will be perfectly fine. But now that we know about this, it is best not to give it to your child until we learn the specifics."

Still, Kroll said he was disappointed that information linking specific medications to specific problems was not available at the time of the recall.

"So, we have no idea which ones are being recalled for potential overdose risk versus those with 'tiny particles,'" he said. "For example, a product with a higher-than-labeled dose of acetaminophen [Tylenol] might be of greater risk than a product with a higher-than-labeled dose of cetirizine [Zyrtec]."