



January 15, 2010

Dear Healthcare Professional:

I am writing to inform you that, in consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is voluntarily recalling certain lots of over-the-counter (OTC) products in the Americas, the United Arab Emirates (UAE), and Fiji (Please see full recalled product list at [www.mcneilproductrecall.com](http://www.mcneilproductrecall.com)). The company is initiating this recall following an investigation of consumer reports of an unusual moldy, musty, or mildew-like odor that, in a small number of cases, was associated with temporary and non-serious gastrointestinal events. These include nausea, stomach pain, vomiting, or diarrhea. This precautionary action is voluntary and has been taken in consultation with the FDA. McNeil is providing the following information to consumers on its [www.mcneilproductrecall.com](http://www.mcneilproductrecall.com) Web site.

**MCNEIL CONSUMER HEALTHCARE ANNOUNCES VOLUNTARY RECALL OF CERTAIN OVER-THE-COUNTER (OTC) PRODUCTS IN THE AMERICAS, UAE, AND FIJI**

In consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is voluntarily recalling certain lots of OTC products in the Americas, the United Arab Emirates (UAE), and Fiji. The company is initiating this recall following an investigation of consumer reports of an unusual moldy, musty, or mildew-like odor that, in a small number of cases, was associated with temporary and non-serious gastrointestinal events. These include nausea, stomach pain, vomiting, or diarrhea. This precautionary action is voluntary and has been taken in consultation with the FDA.

Based on this investigation, McNeil Consumer Healthcare has determined that the reported uncharacteristic smell is caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). This can result from the breakdown of a chemical that is sometimes applied to wood that is used to build wood pallets that transport and store product packaging materials. The health effects of this chemical have not been well studied, but no serious events have been documented in the medical literature. A small number of the product lots being recalled were associated with the complaints of an unusual moldy, musty, or mildew-like odor, and some of these lots were found to contain trace amounts of TBA. In December 2009, McNeil Consumer Healthcare also recalled all lots of **TYLENOL® Arthritis Pain 100 count with EZ-OPEN CAP** related to this issue. McNeil Consumer Healthcare has now applied broader criteria to identify and remove all product lots that it believes may have the potential to be affected, even if they have not been the subject of consumer complaints.

In addition to the product recall, McNeil Consumer Healthcare is continuing their investigation into this issue and is taking further actions that include ceasing shipment of products produced using materials shipped on these wood pallets and requiring suppliers who ship materials to our plants to discontinue the use of these pallets. We will continue to closely monitor and evaluate the situation and consult with the FDA.

Consumers who purchased product from the lots included in this recall should stop using the product and contact McNeil Consumer Healthcare for instructions on a refund or replacement. For these instructions or information regarding how to return or dispose of the product, consumers should log on to the internet at [www.mcneilproductrecall.com](http://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). Consumers who have medical concerns or questions should contact their healthcare provider. 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](http://www.fda.gov/medwatch).

The affected product lot numbers for the recalled products can be found on the side of the bottle label.

If you have any questions, please call our Medical Affairs Department at 1-800-962-5357 (available Monday-Friday 8 a.m. to 8 p.m. Eastern Time).

Sincerely,

Edwin K. Kuffner, MD  
Vice President, Medical Affairs  
McNeil Consumer Healthcare