Rx UPDATE

January 2010

Tylenol® Recall Expands

On January 15, 2010, in consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare announced an expansion of the voluntary recall of certain lots of various over-the-counter (OTC) products. This is an expansion of a prior recall of all lots of Tylenol® Arthritis Pain 100 count with EZ Open Caps in December 2009. The recall is being expanded as a precaution due to consumer reports of unusual moldy, musty or mildew-like odor that was associated with nausea, stomach pain, vomiting and diarrhea.

The uncharacteristic smell is caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole. The source of this chemical is believed to be the breakdown of another chemical used to treat wooden pallets that transport and store packing materials. McNeil Consumer Healthcare has expanded the criteria to identify and remove all product lots that it believes may have the potential to be affected, even though these products and lots have not been the subject of any consumer reports. McNeil Consumer Healthcare is ceasing the shipment of products produced using materials shipped on these wood pallets and is requiring their suppliers who ship materials to their production plants to discontinue using these wood pallets. The health effects of this chemical have not been well studied and to date all of the observed events reported to McNeil Consumer Healthcare were temporary and non-serious.

This expanded recall impacts an additional 54 million bottles of McNeil Consumer Healthcare products to the initial recall, bringing the total recall to over 60 million bottles. The recall impacts over 27 McNeil Consumer Healthcare products in various packages and quantities. The additional products include:

- Benadryl® Allergy Ultratab™
- Motrin®
- Rolaids® Antacid Tablets
- Simply Sleep® Products
- St. Joseph® Products
- Tylenol®

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Tylenol® Recall Expands (cont.)

What Should I Do About This Expanded Recall?

- Please check to see if you have any of the affected products being recalled by McNeil Consumer Healthcare.
- If you have any of these products, please check the lot number of the medication, which can be found on the side of the bottle label. The published lot numbers of the recalled products can be found at www.mcneilproductrecall.com.
- If the product and lot number match, stop using the product.
- If you have this product, please contact McNeil Consumer Healthcare at 1-888-222-6036 (Monday to Friday 8 a.m. to 8 p.m. EST and Saturday to Sunday 9 a.m. to 5 p.m. EST) for instructions on how to return or dispose of this product. Alternatively, information is available on the Tylenol Web site at www.tylenol.com.
- If you have taken this product and have any medical concerns, please contact your physician.

As part of our pharmacy benefit management services, Catalyst Rx partners with clients, members, physicians, and pharmacies to provide updates regarding medication safety issues, industry news and changes to product availability. Catalyst Rx will continue to carefully monitor the situation and provide updates as appropriate.

Source:
http://www.mcneilproductrecall.com/page.jhtml?id=/include/press.inc