



Missouri Department of Health and Senior Services Recall Alert

Over-The-Counter Drug Recall

The Missouri Department of Health and Senior Services received the following recall alert from the FDA. According to the company, these recalls are being initiated at the wholesale level. No action is required by consumers or healthcare providers and consumers can continue to use the products listed below. The recall was not initiated because of any adverse events reported with the use of these products. The recall includes certain lots of TYLENOL® 8 Hour, TYLENOL® Arthritis Pain, and TYLENOL® upper respiratory products, and certain lots of BENADRYL®, SUDAFED PE®, and SINUTAB® products distributed nationwide.

ORIGINAL RELEASE-----

McNeil Consumer Healthcare Initiates Voluntary Recall Of Certain Over-The-Counter (OTC) Products

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FOR IMMEDIATE RELEASE - January 14, 2011 - In consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. is voluntarily recalling, at the wholesale level, certain lots of TYLENOL® 8 Hour, TYLENOL® Arthritis Pain, and TYLENOL® upper respiratory products, and certain lots of BENADRYL®, SUDAFED PE®, and SINUTAB® products distributed in the United States, the Caribbean, and Brazil. These products were manufactured at the McNeil plant in Fort Washington, PA prior to April 2010, when production at the facility was suspended. The company is initiating the recall as a precautionary measure after an extensive review of past production records found instances where equipment cleaning procedures were insufficient or that cleaning was not adequately documented. It is very unlikely that this impacted the quality of these products.

McNeil Consumer Healthcare is also initiating a voluntary recall of certain product lots of ROLAIDS® Multi-Symptom Berry Tablets distributed in the United States, in order to update the labeling. The company initiated the recall after determining that the product labeling does not include the language “Does not meet USP” as required by regulation.

Both of these recalls are being initiated at the wholesale level. No action is required by consumers or healthcare providers and consumers can continue to use the product. These actions are not being undertaken on the basis of adverse events.

McNeil identified the inadequacies as part of a thorough, proactive product quality and process assessment of all McNeil produced products. As previously announced, McNeil has been implementing a Comprehensive Action Plan at its U.S. manufacturing facilities to improve the quality systems at those sites. This product assessment is a key milestone in the implementation of that plan, and the actions being undertaken as a result of the assessment are part of McNeil's ongoing commitment to ensure that all its products meet the high quality standards that consumers expect.

Consumers can access full product details and other information about the recall on the www.mcneilproductrecall.com⁹ website or by calling our Consumer Care Center at 1-888-222-6036 (available Monday-Friday from 8 a.m. – 8 p.m. ET and Saturday – Sunday, 9 a.m. – 5 p.m. Eastern Time).

Any adverse reactions may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: <http://www.fda.gov/MedWatch/report.htm>¹⁰
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>¹¹. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178