



PRODUCT RECALL INFORMATION

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Click here for information related to the recall of certain lots of TYLENOL® 8 Hour, TYLENOL® Arthritis Pain, TYLENOL® Cold, TYLENOL® Allergy, TYLENOL® Sinus, BENADRYL®, SINUTAB® Sinus, SUDAFED PE® and ROLAIDS® products January 14, 2011

January 14, 2011

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McNeil Consumer Healthcare INITIATES Voluntary Recall of CERTAIN OVER-THE-COUNTER (OTC) PRODUCTS

FOR IMMEDIATE RELEASE – Fort Washington, PA (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.com 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: www.fda.gov/MedWatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

[CLICK HERE](#) FOR RECALL INFORMATION ON CERTAIN PRODUCT LOTS OF RECALLED PRODUCTS

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