Tylenol Extra Strength Caplets, 225 count bottles: Recall - Uncharacteristic Odor

U.S. Food & Drug Administration

ISSUE: McNeil Consumer Healthcare is recalling one product lot of Tylenol Extra Strength Caplets, 225 count bottles, distributed in the U.S. The recall stems from a small number of odor reports, including musty, moldy odor. The uncharacteristic musty, moldy odor has been linked to the presence of trace amounts of a chemical known as 2,4,6-tribromoanisole (TBA). While not considered to be toxic, TBA can generate an offensive odor and has been associated with temporary and non-serious gastrointestinal symptoms.

BACKGROUND: The Tylenol lot ABA619 - which includes 60,912 bottles - was manufactured in February, 2009. The product lot number for the recalled product can be found on the side of the bottle label.

RECOMMENDATION: Consumers who purchased product from the lot included in this recall should stop using the product and contact McNeil Consumer Healthcare, either at www.tylenol.com [1] or by calling 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time) for instructions about receiving a refund or product coupon. Consumers who have medical concerns or questions should contact their healthcare provider.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [2]
- Download form [3] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[06/28/2011 - Press Release [4] - McNeil Consumer Healthcare]

SOURCE [5]

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http://www.mdtmag.com/news/2011/06/tylenol-extra-strength-caplets-225-count-bottles-recall-uncharacteristic-odor

Links:

[1] http://www.tylenol.com
[2] http://www.fda.gov/MedWatch/report.htm
[3] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[4] http://www.fda.gov/Safety/Recalls/ucm261498.htm
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm261509.htm