Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: October 19, 2010

TO: All Local Health Departments
Attn: Chief Food Specialist

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: TYLENOL® 8 Hour Caplets 50 Count Sold in The United States and Puerto Rico

SUGGESTED ACTION: **Recommend notification of affected stores via phone, fax, or e-mail.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

McNeil Consumer Healthcare Announces Voluntary Recall of One Product Lot of TYLENOL® 8 Hour Caplets 50 Count Sold in The United States and Puerto Rico

Consumer Contact:
1-888-222-6036

Media Contact:
Marc Boston,
215-273-7649 (office)
215-429-7034 (mobile)

FOR IMMEDIATE RELEASE - October 18, 2010- Fort Washington, PA – McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling one product lot of TYLENOL® 8 Hour caplets 50 count bottles to the retail level. McNeil is taking this action following a small number of complaints of a musty or moldy odor. The uncharacteristic odor is thought to be caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole. This voluntary action is being taken as a precaution and the risk of adverse medical events is remote. To date, observed events reported to McNeil for this lot were temporary and non-serious.

The product lot number for the recalled product can be found on the side of the bottle label.

FULL RECALLED PRODUCT LIST:

Product Name	Lot Number	UPC Code
TYLENOL® 8 HOUR CAPLET 50 count	BCM155	3 0045-0297-51 8

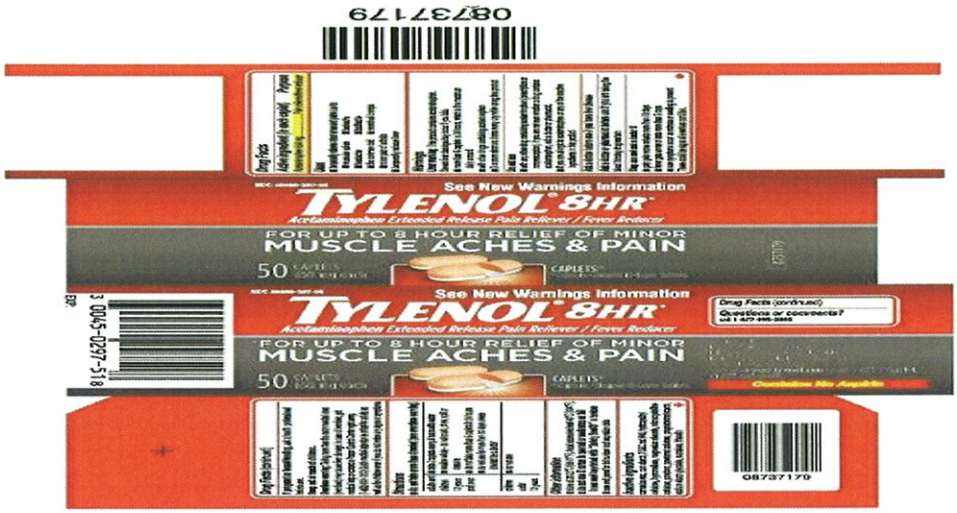
Consumers who purchased product from the lot included in this recall should stop using the product and contact McNeil Consumer Healthcare, either at www.tylenol.com[9] or by calling 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time, and Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time) for instructions about receiving a refund or product coupon. Consumers who have medical concerns or questions should contact their healthcare provider.

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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Photos: Product Labels



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