



**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: June 30, 2011

TO: All Local Health Departments
Attn: Chief Food Inspector Officer

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

SUBJECT: **McNeil Consumer Healthcare Announces Voluntary Recall Of One Product Lot Of TYLENOL® Extra Strength Caplets 225 Count Distributed In The U.S.**

SUGGESTED

ACTION: **Recommend notification of affected stores via phone, fax, or email.**

Consumer inquiry; Consumers who have recently purchased the items should not consume this product and should return it to the store of purchase for a full refund or replacement.

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.

Contact: Consumer:1-888-222-6036

Media:

Marc Boston
215-273-7649 (office)
215-429-7034 (mobile)
Bonnie Jacobs
215-273-8994 (office)
856-912-9965 (mobile)

FOR IMMEDIATE RELEASE - June 28, 2011 - Fort Washington, PA – McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling at the retail level one product lot (60,912 bottles) of TYLENOL®, Extra Strength Caplets, 225 count bottles, distributed in the U.S. The recalled product was manufactured in February, 2009. McNeil is taking this action following 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).

This voluntary action is being taken as a precaution and the risk of serious adverse medical events is remote. TBA can generate an offensive odor and has been associated with temporary and non-serious gastrointestinal symptoms.

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®, Extra Strength Caplets, 225 count	ABA619	300450444271

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.com¹ 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.

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.htm²
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm³. 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).

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