Johnson & Johnson

Mcneil Consumer Healthcare Announces Voluntary Recall of One Product Lot of TYLENOL® Extra Strength Caplets 225 Count Distributed In the U.S.

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.com 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.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

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