



Mitchell E. Daniels, Jr.
Governor

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

DATE: February 17, 2012

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

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

SUBJECT: McNeil Consumer Healthcare Infants' TYLENOL Oral Suspension Recall

SUGGESTED

ACTION: **Unclassified Recall; McNeil Consumer Healthcare is voluntarily recalling, at the wholesale and retail levels, seven lots, approximately 574,000 bottles, of Infants' TYLENOL® Oral Suspension, 1 oz. Grape distributed nationwide in the United States. Infants' TYLENOL® is an over-the-counter (OTC) product indicated as a pain reliever/fever reducer. McNeil is initiating this voluntary recall as a precaution after receiving a small number of complaints from consumers who reported difficulty using the Infants' TYLENOL® SimpleMeasure™ dosing system. Consumers can continue to use Infants' TYLENOL® provided the flow restrictor at the top of the bottle remains in place. If the flow restrictor is pushed into the bottle, the parent or caregiver should not use the product. If any recalled products are found, please notify this office at 317-233-7360.**

Recall -- Firm Press Release

Fort Washington, PA (February 17, 2012) – McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. (“McNeil”), is voluntarily recalling, at the wholesale and retail levels, seven lots, approximately 574,000 bottles, of Infants' TYLENOL® Oral Suspension, 1 oz. Grape distributed nationwide in the United States (see full product list below). Infants' TYLENOL® is an over-the-counter (OTC) product indicated as a pain reliever/fever reducer.

McNeil is initiating this voluntary recall as a precaution after receiving a small number of complaints from consumers who reported difficulty using the Infants' TYLENOL® SimpleMeasure™ dosing system. SimpleMeasure™ includes a dosing syringe, which a parent or caregiver inserts into a protective cover, or “flow restrictor,” at the top of the bottle to measure the proper dose. In some cases, the flow restrictor was pushed into the bottle when inserting the syringe. Children's TYLENOL® products are intended for children two years of age and older and remain available.

No adverse events associated with this action have been reported to date and the risk of a serious adverse medical event is remote. Consumers can continue to use Infants' TYLENOL® provided

the flow restrictor at the top of the bottle remains in place. The company discussed how to use the product's dosing system in a separate message to consumers also issued today.

If the flow restrictor is pushed into the bottle, the parent or caregiver should not use the product.

Consumers can request a refund by visiting www.tylenol.com or contacting McNeil at 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time; Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time). Parents and caregivers with any health questions or concerns should contact their healthcare provider and visit www.tylenol.com for additional information.

FULL RECALLED PRODUCT LIST:

Product Name	Lot Numbers	UPC Code
Infants' TYLENOL® Oral Suspension 1oz. Grape	BIL0U00, BIL0V00, BIL3500, BJL2D00, BJL2E00, BJL2T00, BJL2U00	300450122308

Adverse events that may be related to the use of this product may be reported to U.S. Food and Drug Administration's (FDA) 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 voluntary recall is being conducted with the knowledge of the FDA.

Frequently Asked Questions

http://www.tylenol.com/page.jhtml?id=tylenol/news/faq_feb_2012.inc

Request a refund

https://www.mcneilproductrecall.com/page.jhtml?id=/include/replacement_coupon.inc

Information on Infants' TYLENOL® SIMPLEMENTAL™

http://www.tylenol.com/page2.jhtml?id=tylenol/news/subp_tylenol_recall_9.inc

Information about other TYLENOL® Recalls

<http://www.tylenol.com/page.jhtml?id=tylenol/news/main.inc>