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: July 9, 2010

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 Recall

SUGGESTED ACTION: **Unclassified Recall; 21 lots of over-the-counter medicines; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The lots involved, listed below, are sold in the United States, Fiji, Guatemala, Dominican Republic, Puerto Rico, Trinidad & Tobago, and Jamaica. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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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 Certain Over-The-Counter (OTC) Products in the United States, Fiji, Guatemala, Dominican Republic, Puerto Rico, Trinidad & Tobago, and Jamaica

Contact:
Consumer Inquiries - 1(888) 222-6036
Media Inquiries - Bonnie Jacobs
(215) 273-8994 -office
(856) 912-9965 - mobile

FOR IMMEDIATE RELEASE -- Fort Washington, PA (July 8, 2010) – McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling 21 lots of over-the-counter medicines. The lots involved, listed below, are sold in the United States, Fiji, Guatemala, Dominican Republic, Puerto Rico, Trinidad & Tobago, and Jamaica. This action is a follow-up to a product recall that McNeil Consumer Healthcare originally announced on January 15, 2010, which was initiated following consumer complaints of a musty or moldy odor, which has been linked to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). The risk of serious adverse medical events is remote. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

These lots are being added to the list of recalled products as a precautionary measure after a continuing internal review determined that some packaging materials used in the lots had been shipped and stored on the same type of wooden pallet that was tied to the presence of TBA in earlier recalled lots. All lots involved in the recall were produced before the January 15, 2010 recall, after which McNeil stopped accepting shipments of materials from its suppliers on that type of pallet.

Consumers who purchased product from the lots included in this recall should stop using the product and contact McNeil Consumer Healthcare for instructions on a refund or replacement. For these instructions, and information regarding how to return or dispose of the product, consumers should log on to the internet at www.mcneilproductrecall.com[1] or call 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). Consumers who have medical concerns or questions should contact their healthcare provider.

Any adverse reactions may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/safety/medwatch/default.htm.[2]

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

FULL RECALLED PRODUCT LIST:

Product Name	Lot Number	UPC Code
BENADRYL® ALLERGY ULTRATAB™		
BENADRYL® ALLERGY ULTRATAB™ TABLETS 100 count	ABA567	312547170338
BENADRYL® ALLERGY ULTRATAB™ TABLETS 100 count	ABA574	312547170338
Children's TYLENOL® Meltaways		
CHILDREN'S TYLENOL® MELTAWAYS BUBBLEGUM 30 count	ABA544	300450519306
MOTRIN® IB		
MOTRIN® IB CAPLET 24 count	ACA003	300450481030
MOTRIN® IB CAPLET bonus pack 50+25 count	ACA002	300450481764
MOTRIN® IB TABLET 100 count	AFA060	300450463043
TYLENOL®, Extra Strength		
TYLENOL®, Extra Strength EZ TABLET 225 count	ASA206	300450422378
TYLENOL®, Extra Strength EZ TABLET 50 count	ABA005	300450422507
TYLENOL®, Extra Strength COOL CAPLET 24 count	ABA566	300450444240

TYLENOL®, Extra Strength CAPLET bonus pack 24+12 count	ACA025	300450444318
TYLENOL®, Extra Strength CAPLET 50 count	AFA018	300450449078
TYLENOL®, Extra Strength CAPLET 50 count (included in Day/Night Pack)	ABA168	300450444530
TYLENOL®, Day & Night Value Pack (contains Extra Strength CAPLET 50 count Lot # ABA168 & UPC 300450444530)	AEC005	300450527103
TYLENOL®, Day & Night Value Pack (contains Extra Strength CAPLET 50 count Lot # ABA168 & UPC 300450444530)	AFC005	300450527103
TYLENOL®, Day & Night Value Pack (contains Extra Strength CAPLET 50 count Lot # ABA168 & UPC 300450444530)	ADC002	300450527103
TYLENOL®, Extra Strength RAPID RELEASE GELCAP 24 count	ACA024	300450488244
TYLENOL®, Extra Strength RAPID RELEASE GELCAP 225 count	AJA119	300450488251
TYLENOL® PM		
TYLENOL® PM CAPLET 24 count	ACA005	300450482242
TYLENOL® PM CAPLET 24 count	ADA259	300450482242
TYLENOL® PM GELTAB 50 count	AFA100	300450176509
TYLENOL® PM RAPID RELEASE GELCAP 20 count	ACA004	300450244208

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