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 17, 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 Expanded Recall

SUGGESTED ACTION: **Unclassified Recall; Consumer complaints of a musty or moldy odor that has since been linked to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA); 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. BENADRYL® ALLERGY ULTRATAB™ TABLETS is sold over-the-counter and is indicated for the relief of allergy associated symptoms such as sneezing, runny nose, itchy throat, and itchy and watery eyes. 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 Recalls Four Product Lots of Benadryl® Allergy Ultratab™ Tablets, 100 Count, and One Product Lot of Extra Strength Tylenol® Rapid Release Gels, 50 Count

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FOR IMMEDIATE RELEASE - Fort Washington, PA - June 15, 2010 - McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling five product lots as an addition to the list

of products included in the company's January 15th, 2010 product recall. The additional lots involved are four product lots of BENADRYL® ALLERGY ULTRATAB™ TABLETS, 100 count, sold in the U.S.; and one product lot of EXTRA STRENGTH TYLENOL® Rapid Release Gels, 50 count sold in the U.S., Trinidad and Tobago, Bermuda, and Puerto Rico (FULL RECALLED PRODUCT LIST BELOW). This recall is a follow-up to the product recall that McNeil Consumer Healthcare announced on January 15th, 2010 and is being taken because the products were inadvertently omitted from the initial recall action. McNeil Consumer Healthcare identified the omission and informed the U.S. Food and Drug Administration (FDA) of its decision to add these product lots to the recall list. All these products were produced before the January 15th, 2010 recall. Since January, McNeil Consumer Healthcare has continued to analyze and evaluate 2,4,6-tribromoanisole (TBA) and has shared that information with the FDA. This further analysis confirms that the risk of serious adverse medical events is remote. This recall is being conducted with the knowledge of the FDA.

BENADRYL® ALLERGY ULTRATAB™ TABLETS is sold over-the-counter and is indicated for the relief of allergy associated symptoms such as sneezing, runny nose, itchy throat, and itchy and watery eyes. EXTRA STRENGTH TYLENOL® Rapid Release Gels is sold over-the-counter and is indicated for the temporary reduction of fever and for the temporary relief of minor aches and pains due to headache, muscular aches, backache, minor arthritis pain, the common cold, toothache, pre-menstrual and menstrual cramps, and flu.

The January 15th, 2010 recall was initiated as a result of consumer complaints of a musty or moldy odor that has since been linked to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). After a thorough investigation, it was determined that the source of TBA was the result of a breakdown of a chemical that is applied to wood used to build wooden pallets that transport and store product packaging materials.

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 or 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). Requests for reimbursement can be made at www.mcneilproductrecall.com[2]. 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 http:www.fda.gov/safety/medwatch/default.htm.

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

FULL RECALLED PRODUCT LIST:

Product Name	Product Form	Lot Number	NDC Number	UPC Code
BENADRYL Allergy ULTRATAB Tablets 100 count	Ultratab Tablet	AJA008, ADA194, ABA022, ABA264	50580-226-10	312547170338
EXTRA STRENGTH Tylenol Rapid Release Gels 50 count	Rapid Release Gelcap	ASA202	50580-488-50	300450488503