Rx UPDATE

December 2009

Recall of Tylenol® Arthritis Pain Caplets

On December 28, 2009, McNeil Consumer Healthcare and the U.S. Food and Drug Administration (FDA) announced the voluntary recall of all lots of Tylenol® Arthritis Pain Caplet 100-count bottles, with the distinctive red EZ-Open Cap. This is an expansion of a limited recall previously announced in November 2009 for five lots of this product. The recall was expanded as a precaution due to consumer reports of an unusual moldy, musty or mildew-like odor that was associated with nausea, stomach pain, vomiting and diarrhea.

The uncharacteristic smell is caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole. The source of this chemical is believed to be the breakdown of another chemical used to treat wooden pallets that transport and store packing materials. The health effects of this chemical have not been well studied and, to date, all of the observed events reported to McNeil Consumer Healthcare were temporary and non-serious.

Only Tylenol Arthritis Pain Caplet 100-count bottles with the red EZ-Open Cap are affected by this recall. All other Tylenol Arthritis Pain products remain commercially available and are not affected by this recall. A complete list of affected lots is below.

UPC Code	Code #	Lot Numbers
0045-0838-21	8382100	07CMC011, 07DMC022, 07DMC024, 07FMC032, 07FMC033, 07GMC038, 07GMC039, 07HMC045, 07HMC051, 07HMC053, 07JMC064, 07JMC069, 07JMC070, 07JMC071, 07XMC055, 07XMC058, 07XMC062, 08AMC002, 08AMC005, 08CMC026, 08DMC029, 08EMC037, 08EMC039, 08FMC044, 08FMC045, 08GMC050, 08GMC053, 08GMC063, 08GMC065, 08JMC103, 08JMC109, 08JMC110, 08JMC111, 08KMC124, 08KMC127, 08KMC131, 08KMC132, 08XMC093, 08XMC094, 08XMC095, 09AMC010, 09CMC041, 09EMC075, 09EMC079, 09EMC076, 09GMC096, 09GMC097, 09GMC099, 09JMC118, 09JMC126, 09KMC133, 09KMC134, 09XMC114, 09XMC116

Individuals in possession of Tylenol Arthritis Pain Caplet 100-count bottles with a red EZ-Open Cap are instructed to not use the product and to contact McNeil Consumer Healthcare at 1-888-222-6036 (Monday-Friday 8:00 a.m. to 8:00 p.m. Eastern Time and Saturday-Sunday 9:00 a.m. to 5:00 p.m. Eastern Time) for instructions on how to return or dispose of this product. Medical concerns related to taking this product should be directed to the individual's physician.

McNeil Consumer Healthcare is planning on re-introducing the Tylenol Arthritis Pain Caplet 100-count bottle in January 2010 by moving the production of this product to a new facility.

As part of our pharmacy benefit management services, Catalyst Rx partners with clients, members, physicians, and pharmacies to provide updates regarding medication safety issues, industry news and changes to product availability. Catalyst Rx will continue to carefully monitor the situation and provide updates as appropriate.

Sources:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm195704.htm
http://www.tylenol.com/page2.jhtml?id=tylenol/news/subp_tar_recall.inc

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