



Re: McNeil Consumer Healthcare Voluntary Recall

Dear Healthcare Professional:

December 18, 2009

I am writing to inform you that, in consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare is initiating a voluntary recall of currently available lots of TYLENOL® Arthritis Pain Caplet 100 count bottles, with the distinctive red EZ-OPEN CAP. In November 2009, 5 lots of this product were recalled due to consumer reports of an unusual moldy, musty or mildew-like odor that was associated with nausea, stomach pain, vomiting and diarrhea. The recall is being expanded, as a precaution, to include all TYLENOL® Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP.

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

McNeil is providing the following information to consumers on its www.tylenol.com Web site.

TYLENOL® ARTHRITIS PAIN 100 COUNT WITH EZ-OPEN CAP RECALLED.

In consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, a Division of McNEIL-PPC, Inc., is voluntarily recalling all currently available bottles of TYLENOL® Arthritis Pain Caplet 100 count. These bottles can be easily identified by a distinctive red EZ-OPEN CAP. In November 2009, 5 lots of this product were recalled due to consumer reports of an unusual moldy, musty or mildew-like odor that was associated with nausea, stomach pain, vomiting and diarrhea. The recall is being expanded, as a precaution, to include all TYLENOL® Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP. Only the TYLENOL® Arthritis Pain Caplet 100s are affected by this action. All other TYLENOL® Arthritis Pain products remain available. McNeil Consumer Healthcare will reintroduce the TYLENOL® Arthritis Pain Caplet 100 count product by January 2010.

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If you have purchased TYLENOL® Arthritis Pain Caplet 100 count bottles with the EZ-Open Cap, you should stop using the product and contact McNeil for instructions on a refund or replacement. For these instructions or information regarding how to return or dispose of the product, please 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) or use our email contact form.

If you have medical concerns or questions, please contact your healthcare provider.

The affected TYLENOL® Arthritis Pain Caplet 100 count product lot numbers can be found on the side of the bottle label. See the full list of affected product lot numbers below:

Recalled Products - Full List			
UPC #	Code #	LOT #	Product Description
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	TYLENOL® ARTHRITIS PAIN CAPLET 100 COUNT BOTTLES (with red EZ-OPEN CAP)

If you have any questions, please call our Medical Affairs Department at 1-800-962-5357 (available Monday-Friday 8 a.m. to 8 p.m. Eastern Time).

Sincerely,

Edwin K. Kuffner, MD
Vice President, Medical Affairs
McNeil Consumer Healthcare