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# FDA Slams Tylenol Maker's Delay in Tainted Pill Recall

More Products, Including Tylenol Extra Strength and Roloids, Recalled Due to Noxious Chemical Fears

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The U.S. Food and Drug Administration slammed Tylenol manufacturer McNeil Healthcare LLC during a media briefing Friday morning for what it called a slow response to problems at a facility in Puerto Rico that led to consumers becoming sickened by tainted pills.

"McNeil should have acted faster," said Deborah Autor, director of the FDA's Office of Compliance, of the arm of Johnson & Johnson that manufactures Tylenol products, adding "When something smells bad, literally or figuratively, they must aggressively investigate and solve the problem."

A recall of Tylenol products has expanded to include more than two dozen other over-the-counter products manufactured by McNeil. The broadened directive adds 54 million bottles of product to the recall, boosting the total number of bottles recalled by McNeil to approximately 60 million, according to the company.

McNeil initiated a voluntary recall of [Tylenol Arthritis Relief Caplets](#) at the end of December after consumer complaints of stomach problems. The problems were linked to the presence of a chemical called 2,4,6-tribromoanisole (TBA), which results from the breakdown of a chemical in wood pallets used to transport and store packaging materials for the drugs.

Now it appears that the problem extended into other [Tylenol](#) products as well, according to the FDA. Tylenol Extra Strength, Roloids and a number of children's medicines are now included in the recall, which affects 27 products in various packaging quantities.

McNeil released a statement today in which it said the voluntary recall is being conducted in consultation with the FDA and affects a number of products for which there have been no complaints. The company added that the musty-smelling chemical thought to be the cause of the sickness posed no fatal risk to those who ingest it.

"The health effects of this chemical have not been well studied, but no serious events have been documented in the medical literature," the statement read.

"In addition to the product recall, McNeil Consumer Healthcare is continuing its investigation into the issue and is taking further actions that include ceasing shipment of products produced using materials shipped on these wood pallets and requiring suppliers who ship materials to our plants to discontinue the use of these pallets."

In its statement, the company advised consumers who purchased the affected products to stop using them and contact McNeil for information about how to get a refund or a replacement. The company provided the address for its Web site, [www.mcneilproductrecall.com](http://www.mcneilproductrecall.com), as well as a toll-free number: (888) 222-6036.

Prior to today's recall, the FDA had cited at least two of the company's products in a letter to McNeil, as these products had been the subject of complaints about an "uncharacteristic smell," similar to the one that helped trigger the [recall](#) of the arthritis caplets.

"Since the date of the discovery, your firm did not extend the assessment of the event to other products that received packaging components from the same supplier," said the FDA's letter, which was signed by Jose R. Lopez, an investigator, and Raquel Gonzalez Rivera, a chemist. The letter goes on to cite over 10 "musty-moldy odor" complaints about Roloids and over 39 similar complaints about Tylenol Extra Strength, "including three adverse event reports." The letter is dated Jan. 8, 2010, but was posted to the FDA's Web site Jan. 13.

"Certainly, the FDA report raises serious questions about the manufacturer's response," said Robert Field, professor of health management and policy at the Drexel University School of Public Health. "The report has found that the investigation was limited...that the procedures for quality control were not in writing...and various other lapses that were fairly significant."

The FDA report further criticized McNeil for inadequate responses to complaints, noting that they first received heightened complaints about the musty odor in 2008 and testing confirmed its presence in September of that year.

"Your quality unit failed to conduct additional testing to evaluate the possibility of chemical contamination or other change or deterioration in the distributed drug product," the FDA letter says.

Karen Hirshfield, acting branch chief of the FDA Office of Compliance's Recalls and Shortages Branch, revisited these concerns during this morning's briefing.

"We would have expected McNeil to expand their investigation when they first learned of consumer complaints on this issue," she said. "They became aware of a problem in September 2008, and their investigation and report to [the FDA] didn't occur until about a year later. We would have expected action to occur sooner than that."

Meanwhile, current problems with Roloids and Tylenol Extra Strength are attributed to another testing failure. "Investigations of an unexplained discrepancy did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy," the report said.