

## **FDA: Johnson & Johnson Unit Too Slow With Tylenol Recall**

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WASHINGTON (Dow Jones)--The U.S. Food and Drug Administration said a Johnson & Johnson (JNJ) unit should have acted sooner to recall Tylenol and other products after receiving consumer complaints about moldy or mildew-like smells.

Agency officials said Friday the company first became aware of a problem in September 2008, but didn't conduct a full investigation and report the problem to the agency until September 2009.

"When something smells bad literally or figuratively companies must aggressively investigate," said Deborah Autor, the director of FDA's Office of Compliance. She said the agency issued a warning letter to McNeil Consumer Healthcare, the J&J unit that makes over-the-counter Tylenol products, for violating agency reporting rules and the agency's manufacturing practice rules. The warning letter wasn't immediately available.

Earlier Friday, the company said it was voluntarily expanding a recall of several over-the-counter products, including certain lots of over-the-counter products Tylenol, Motrin, Benadryl and St. Joseph Aspirin.

The company has received reports that some of the products may have caused nausea and other stomach problems. The FDA said the nausea and stomach problems were temporary.

The FDA said the total recall involves about 500 lots, which would total about 50 million bottles.

McNeil first recalled some Tylenol products in November 2009 while FDA investigators were inspecting a company plant in Puerto Rico. That inspection stretched from October 2009 through Jan. 8, 2010. Autor said the FDA had "urged" the company to recall the products.

It's unclear what effect the recall will have on Johnson & Johnson's business. The company's chief operating officer said last year Tylenol has about \$1 billion in sales in the U.S. annually.

The FDA warning comes as the agency has been increasingly enforcing its rules and regulations under the Obama administration. "All drug manufacturers have a corporate responsibility to ensure their products are high quality, safe and effective," Autor said during a conference call with reporters. "When a problem arises with their products they must be proactive, quick and thorough."

The company and the FDA said the moldy smell reported by consumers was caused by trace amounts of a chemical that is sometimes applied to wood pallets used to store and transport Tylenol, Rolaid's and other products.

Autor said the FDA is currently trying to determine whether other companies use pallets that contain the chemical.

The FDA announcement comes days after the agency released a report showing the company failed to test whether its pain reliever Tylenol was chemically contaminated despite receiving a heightened number of consumer complaints in 2008 that the pills smelled musty. The report followed the Puerto Rico plant inspection.

Not all the products being recalled are from the company's plant in Puerto Rico. The company said in a statement it is recalling some products for which it hasn't received consumer complaints.

The report also said the company also didn't test whether chemically treated wood pallets caused moldy odor in the heartburn medication Rolaid's. The FDA said consumers had filed more than 10 consumer complaints of moldy-smelling Rolaid's.