

# **FDA Barrs J&J From Manufacturing After Recalls**

Matthew Perrone, AP Health Writer

WASHINGTON (AP) — Federal officials said Thursday that the consumer health unit of Johnson & Johnson will be barred from resuming operations at a Pennsylvania manufacturing plant linked to millions of bottles of defective medicines until it meets quality standards.

The Food and Drug Administration signed a formal consent decree with the company designed to improve operations at three manufacturing sites linked to multiple recalls of medications last year, including Children's Tylenol, Benadryl and Motrin. The FDA said J&J's McNeil Consumer Healthcare unit violated the law in its production of medications and will be subject to fines of up to \$10 million annually if it does not comply with the decree. McNeil undertook its own corrective action plan beginning last July, but violations at the plants have persisted, according to the government filing.

J&J has issued 20 recalls since September 2009 covering over-the-counter medicines like Children's Tylenol and Benadryl, plus contact lenses and hip replacements.

Under terms of the agreement, the company's Fort Washington, Pa., plant will remain closed until it has been inspected and certified by an outside inspector and the FDA. The plant produced most of J&J's liquid cold medications before it was closed last April. FDA inspectors cited the facility for a slew of problems including releasing medicines with the wrong doses of active ingredient and contamination with bacteria or tiny metal shards.

While the decree means J&J will face regulatory scrutiny for at least five years, it was not immediately required to pay any fines and has been allowed to continue to operate its plants in Las Piedras, Puerto Rico and Lancaster, Pa. Both plants also were named in the agreement.

FDA's drug compliance director Deborah Autor called the latest action "a strong, but necessary step."

J&J CEO William Weldon said the company is taking responsibility for its mistakes.

"We are a company that strives to do the right thing, and we succeed far more often than not," Weldon wrote in a note to employees posted on a company website. "When we don't succeed, it's painful."

The agreement, filed in the U.S. District Court for the Eastern District of Pennsylvania, requires J&J to destroy all recalled drugs that have been returned to the company within 30 days. The decree also sets strict deadlines for arranging for an independent expert to inspect the plants and recommend improvements. Based

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on those findings, J&J will develop remediation plans which will be submitted to the FDA for approval.

In its last quarter the New Brunswick, N.J.-based company reported a 12 percent drop in profit, as sales were squeezed by a weak economy, pricing pressures and recalls that have kept many popular nonprescription medicines off store shelves. Sales of the company's over-the-counter medicines fell more than 19 percent last year.

Company shares fell 79 cents to close at \$59.61 Thursday.

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