

FDA inspectors found lax testing for contamination at J&J's Tylenol production site

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WASHINGTON (AP) — Ingredients used by Johnson & Johnson in some of the 40 varieties of children's cold medicines recalled last week were contaminated with bacteria, according to a report by the Food and Drug Administration.

Agency officials said Tuesday none of the company's finished products tested positive for the contaminants, though such testing is not definitive.

"We think the risk to consumers at this point is remote," said Deborah Autor, director of FDA's drug compliance office, on a call with reporters.

The FDA report, which was posted online, lists more than 20 manufacturing problems found at the McNeil Consumer Healthcare plant in Fort Washington, Pa., where the formulas were made. The recalled products include children and infant formulations of Tylenol, Motrin, Zyrtec and Benadryl.

FDA inspectors visited the plant in mid-April and wrapped up their inspection Friday. J&J issued its "voluntary" recall later that night.

Among other problems, FDA inspectors said the company did not have laboratory facilities to test drug ingredients and failed to follow up on customer complaints.

J&J did not investigate more than 46 complaints received in the last year about "black or dark specks" in Tylenol products, according to the FDA's report.

Additionally, inspectors found some pieces of equipment covered with thick layers of dust, while others were held together with duct tape.

In a statement Tuesday, J&J called the problems cited by the FDA "unacceptable to us, and not indicative of how McNeil Consumer Healthcare intends to operate." The health conglomerate, which is based in New Brunswick, N.J., said production at the plant won't resume until the problems have been fixed.

The FDA reiterated that serious medical problems with the products are unlikely, but advised consumers to stop using the medicine as a precaution. Parents are instructed to use generic alternatives instead.

J&J's McNeil Consumer Healthcare unit has said some of the recalled medicines may have a higher concentration of the active ingredient than listed on the bottle. Others may contain

particles, while still others may contain inactive ingredients that do not meet testing requirements.

FDA leadership told reporters Tuesday that they first met with J&J in February to discuss manufacturing problems identified in a warning letter about another J&J plant. The agency decided to step up inspections of the company's facilities based on those problems.

"That warning letter brought us to the point where we thought it was necessary to sit down with management and discuss our concerns," Autor said.

FDA officials said they are considering taking additional action against J&J, ranging from issuing more warning letters to pursuing criminal action.

Last week's sweeping recall, which involved products sold in the U.S. and 11 other countries, is the latest quality issue to taint J&J's over-the-counter medicine franchise. In January, the company recalled a line of adult Tylenol pain relievers due to complaints of a moldy smell associated with wooden pallets used to transport the drugs.

FDA: Tylenol knowingly used bacteria-contaminated materials

Tests show ingredients in Johnson & Johnson cold medicine were contaminated with bacteria, but finished products did not show bacteria levels

Clair Zakharia WGN News

May 5, 2010

The Food and Drug Administration says the makers of Tylenol cold medicines knowingly used contaminated materials.

Tests showed that ingredients in Johnson & Johnson cold medicines were contaminated with bacteria, but the agency says the finished products did not show bacteria levels.

The voluntarily recalled Tylenol, Motrin, Zyrtec and Benadryl products do appear to be safe. However the FDA is urging parents to use generic medicines while it investigates the company further.

The FDA report lists more than 20 manufacturing problems found at the Fort Washington, Pa., plant where the formulas were produced. Production at the plant is shut down indefinitely.