FDA found bacteria in lots for recalled Tylenol

May 4 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- Ingredients used by Johnson & Johnson in some of the 40 varieties of children's cold medicines recalled last Friday 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 exhaustive.

"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 produced. 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" found in Tylenol products, according to the FDA's report.

In a statement Tuesday, J&J called the problems discovered by the FDA "unacceptable to us, and not indicative of how McNeil Consumer Healthcare intends to operate." The company said production at the Fort Washington plant won't resume until corrective measures have been put in place.

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 to the Tylenol products.

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.

Friday'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 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 point where we thought it was necessary to sit down with management and discuss our concerns," Autor

said.