

New Information: FDA Widens Tylenol Probe

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NEW YORK - The Food and Drug Administration said Monday it is expanding its investigation of a Johnson & Johnson manufacturing division tied to the recent recall of children's drugs.

On May 1, Johnson & Johnson's McNeil Consumer Healthcare unit recalled some 50 children's versions of non-prescription drugs, including Tylenol, Motrin and Benadryl. Then on May 6, the FDA issued a scathing 17-page inspection report of McNeil's Fort Washington, Pa., plant that produced the drugs.

Now the FDA is conducting a company wide investigation of McNeil's "manufacturing practices to determine whether similar problems exist throughout the company and what additional steps the agency must take to ensure that these problems do not recur," according to a statement posted Monday on the FDA website.

In a statement e-mailed to CNNMoney on Monday, McNeil said the company "is conducting a comprehensive quality assessment across its manufacturing operations and continues to cooperate with the FDA."

Johnson & Johnson which subsequently shut the Fort Washington facility, has declined to disclose what other products are manufactured at the plant.

In announcing the recall, McNeil said that some of the children's products may contain incorrect concentration of ingredients, ingredients that don't meet testing requirements and tiny metal particles.

The FDA on Monday declined to comment on how many other facilities it is targeting in the expanded probe.

A McNeil plant in Puerto Rico that makes adult versions of over-the-counter drugs was the focus of a recall in January after the company got complaints of an "unusual moldy, musty or mildew-like" odor in products made at the plant.

The FDA's May 6 report about the Fort Washington plant listed 20 violations. In one of them, the agency said McNeil had taken no action after receiving 46 consumer complaints on the recalled products.

The company and the FDA have said that the recalled children's drugs pose a "remote" potential for serious health problems.

A congressional committee has opened an investigation into the recall.

The story is from CNN in Atlanta, GA.