FDA Scrutinizes Another J & J Manufacturing Facility

by Linda A. Johnson, AP Business Writer

TRENTON, N.J. (AP) — A second Johnson & Johnson medicine factory is under scrutiny from federal regulators, while the company struggles to deal with bad publicity and repeated recalls at another factory.

The healthcare giant in April shut down a plant in Fort Washington, a Philadelphia suburb, that's now linked to eight recalls of Tylenol and other nonprescription drugs for children and adults.

Now the Food and Drug Administration has sent the company a critical report after a recent inspection found problems at another Pennsylvania plant, in Lancaster.

New Brunswick, N.J.-based J&J said Monday that it's addressing the FDA's concerns as quickly as possible.

The news comes just before Johnson & Johnson is to release its second-quarter earnings results Tuesday morning, followed by a conference call with analysts who are sure to grill company executives about the repeated problems.

An FDA official two months ago told Congress the agency had broadened its investigation beyond the Fort Washington plant and also had turned the case over to its Office of Criminal Investigations.

The Lancaster plant is operated by a joint venture called Johnson & Johnson/Merck Consumer Pharmaceuticals Co. The business sells products, including heartburn medicine Pepcid, that originally were sold as prescription drugs and now are available in over-the-counter, lower-dose versions. Merck & Co. of Whitehouse Station, N.J., is J&J's partner in the operation.

FDA spokeswoman Elaine Gansz Bobo said the report is still under review and cannot be released publicly until sensitive commercial information has been blacked out. That's the agency's standard practice.

She said she did not know "the scope and nature of the deficiency."

The report, called a Form 483, is issued when an FDA inspection finds deficiencies at a pharmaceutical manufacturing plant.

Johnson & Johnson confirmed that the joint venture had received the Form 483 report from the FDA after a recent inspection at its Lancaster plant. Company

spokeswoman Bonnie Jacobs declined to say when the inspection occurred or exactly what it found.

In a statement, the joint venture said it "takes the issues raised by the agency seriously and is fully committed to addressing their concerns as rapidly as possible. We will provide a detailed response to the FDA and work diligently to address all observations."

The series of recalls at the Fort Washington plant have been caused by problems including contamination with bacteria, a nauseating smell on containers, possible problems with the wrong amount of active ingredient and liquid medicines that may contain tiny metal shavings.

That factory makes nonprescription pain relievers, allergy medicine, sleeping pills and heartburn tablets. The recalled products include liquid Tylenol for infants and children, Tylenol arthritis caplets, Motrin, Benadryl, Rolaids, St. Joseph's aspirin and Simply Sleep.

Last Thursday, Johnson & Johnson said the factory, closed in April, will remain shut down for at least another year while it replaces and upgrades manufacturing and testing equipment. About 300 of the plant's 400 workers will lose their jobs.

Besides the eight announced recalls, Johnson & Johnson allegedly had another company quietly remove bottles of Motrin with potency problems from store shelves in 2008. J&J did not announce a recall then, and the action now is the subject of a congressional investigation.

In trading Monday afternoon, Johnson & Johnson shares closed up 13 cents at $59.57.