FDA: J&J delayed reporting insulin pump problems

January 11 2012, By LINDA A. JOHNSON , AP Business Writer

(AP) -- Federal regulators have warned Johnson & Johnson that it could face fines and other sanctions for selling faulty insulin pumps and delaying disclosures of serious injuries to diabetics who were using its OneTouch Ping and 2020 pumps.

The Food and Drug Administration ordered J&J's Animas Corp. unit to explain why it kept selling pumps known to fail and also to submit a plan to rectify its failure to promptly report cases where its device might have caused or contributed to death or serious injury.

In a Dec. 27 warning letter posted online by FDA Tuesday, the agency wrote to Animas and J&J CEO Bill Weldon that inspectors found Animas, which is based in West Chester, Pa., never reported on one complaint about serious patient injury and delayed reporting on two others. Those patients were hospitalized with dangerously high blood sugar, respiratory failure and coma, and a life-threatening complication called diabetic ketoacidosis caused by lack of insulin to break down blood sugar.

Insulin pumps, which are about the size of a cellphone, automatically inject small amounts of insulin through a tiny needle under the skin throughout the day to keep diabetics' blood sugar at a safe level. Patients program the device to inject additional insulin right before a meal or snack, according to the amount of carbohydrates about to be eaten.

Animas spokeswoman Caroline Pavis said in an interview that the

company did not report the three patient incidents to FDA as required within 30 days because each involved patients not using the pumps according to directions. In one case, she said, the patient ignored an alarm signaling the cap had come off the insulin cartridge inside the device, preventing insulin from being pumped into the body. She said Animas will now report all patient complaints promptly.

In a separate issue, some pump keypads for controlling how much insulin is injected were deteriorating prematurely, leading to failures.

"We decided to go with a new keypad because it's more durable," Pavis said.

But while Animas was lining up the new keypad supplier, it was still selling the older ones. The FDA demanded documents about the company's decision to do that.

David Rosen, a former FDA staff member who's now an attorney at Foley & Lardner LLP advising clients on FDA regulatory issues, said companies must continuously evaluate a product's safety over its life span.

"A company the size of J&J should have infrastructure in place to process, review and classify complaints, because they could be indicative of a larger issue with the product," he said. "It's a little disconcerting that they didn't have their act together in that regard."

The problems follow a string of nearly 30 product recalls announced by New Brunswick, N.J.-based Johnson & Johnson from September 2009 through last month. They have included millions of bottles of Tylenol, Motrin and other nonprescription medicines for children and adults, prescription drugs for seizures and HIV, faulty hip implants and contact lenses that stung the eyes. Reasons for the recalls ranged from

contamination with metal shards and glass particles, to nauseating odors and inaccurate levels of active drug ingredients.

"Any company can have one of these things pop up and smack them, and you can have a bad coincidence when two of them come and smack you three weeks apart. But it's not bad luck when you have" this many, said Erik Gordon, a professor and analyst at the University of Michigan's Ross School of Business. "The amazing thing is that Bill Weldon still has a job."

The recalls cost J&J $900 million in 2010 alone in lost revenue from products not being in stores, plus millions more for factory upgrades and legal expenses. The FDA and Congress have been investigating the handling of the manufacturing problems and the recalls by a company that stresses in its corporate credo its responsibility to the doctors, patients and parents who use its products.

J&J has said there have been no reports of serious patient harm from the recalled products, although it's now being sued by a couple alleging their toddler died from taking a "super dose" of defective Children's Tylenol.

The FDA's warning letter states that the initial Animas response to the problems cited in the August inspection report was not adequate. Pavis said Animas hopes to respond before the Jan. 20 deadline.

The letter states that if the company doesn't promptly correct the violations, it could face seizure, injunction, and fines, and could be denied future contracts from federal agencies. Pavis could not say how much business Animas does with the Medicare and Medicaid programs.

On Wednesday, Johnson & Johnson shares fell 7 cents to close at $65.13.