FDA: Novartis recall may also affect painkillers

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(AP) -- The Food and Drug Administration is warning patients about a potential mix-up between powerful prescription pain drugs and common over-the-counter medications like Excedrin and Gas-X made at a Novartis manufacturing plant.

The problem stems from major manufacturing problems at a Lincoln, Neb., facility which triggered a sweeping recall of the company's over-the-counter drugs on Sunday. The company has received complaints of broken and chipped pills, and inconsistent bottle packaging that could cause pills to be mixed up. Consumers should not use the products and can contact the company for a refund.

FDA officials warned Monday that some of Novartis' over-the-counter pills may have accidentally been packaged with powerful prescription painkillers made at the same facility. The opioid drugs are sold by Endo Pharmaceuticals as Percocet, Endocet, Opana and Zydone.

Endo Pharmaceuticals Holdings Inc., of Chadds Ford, Pa., said it is not aware of any confirmed product mix-ups or injuries.

FDA officials say they are not recalling the painkillers because they are essential medications for many patients and the risks of stray pills are low.

"The likelihood of finding a wrong tablet in an opiate pain medication dispensed to patients is low and patients should not be unduly alarmed,"

FDA's Dr. Edward Cox told reporters.

Cox said regulators are also concerned about a shortage of Endo's painkillers in coming weeks due to the shutdown of the Nebraska facility. Switzerland-based Novartis voluntarily halted production at the plant last month.

"FDA is working with Endo and Novartis to minimize the degree of impact. The degree of shortage will depend upon how quickly safeguards can be put in place to prevent this manufacturing issue from happening in the future," the FDA said in a statement on its website.

FDA inspectors cited Novartis' plant for dozens of quality control problems last summer, in a report posted to the agency's website. Company officials repeatedly failed to properly follow up on consumer complaints received since 2009. FDA inspectors concluded that none of the 223 complaints received by the plant last year were properly reviewed, according to the report.

Novartis announced Sunday it would recall certain bottles of headache medicine Excedrin and caffeine caplets NoDoz with expiration dates of Dec. 20, 2014. The company is also recalling some packages of pain medicine Bufferin and stomach medicine Gas-X with expiration dates of Dec. 20, 2013, or earlier.

Customers can also call the company at 1-888-477-2403 Monday to Friday, 9 a.m. to 8 p.m. EST.

The FDA and Endo Pharmaceuticals recommend patients examine their prescriptions to make sure all the tablets are similar in shape, color, size and marking. If one or more of the tablets look different, patients should return the medicine to their pharmacist.

Patients can call Endo Pharmaceuticals' call center at 1-800-462-3636.