

## **FDA: Novartis recall may also affect painkillers**

By MATTHEW PERRONE, AP Health Writer – Jan 9, 2012

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

The issue stems from manufacturing problems at a Lincoln, Nebraska, facility which triggered a recall Sunday of 1,645 lots of Novartis' over-the-counter drugs, including Excedrin, Bufferin, NoDoz and Gas-X. The Swiss-based company has received hundreds of complaints of broken and chipped pills and inconsistent bottle packaging that could cause pills to be mixed up. Consumers are advised to stop using the products and 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, Pennsylvania, said it is not aware of any confirmed product mix-ups that reached patients or caused any injuries. A spokeswoman for Novartis said late Monday that only Gas-X is produced on the same manufacturing line as the opioid drugs.

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 FDA inspectors are currently inspecting the plant and uncovered a manufacturing problem that could allow pills to become stuck in the machinery and carry over to the packaging of other products. FDA officials said the investigation is ongoing and would not comment on potential penalties against Endo or Novartis.

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.

Cox said regulators are also concerned about a shortage of Endo's painkillers in coming weeks due to the shutdown of the Nebraska facility. Novartis voluntarily halted production at the plant Dec. 19.

"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 a dozen quality control problems last summer, in a report posted to the agency's website. Company officials failed to properly investigate 166 complaints of mixed-up pills found in Novartis bottles since 2009, according to inspectors. The inspectors also concluded that none of the 223 customer complaints received by the plant last year were adequately reviewed, according to the report.

Novartis AG said in a statement said that it issued the recall "at the appropriate time ... as a precautionary measure in the best interest of consumers." The Basel, Switzerland-based company said it is working to upgrade and improve manufacturing and training at the Nebraska plant.

The company 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.