



Page 7B

FDA guidelines call for radio technology to control counterfeit drugs Drugmakers will use RFIDs to track products

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USA TODAY

The Food and Drug Administration on Monday issued guidelines it hopes will prompt drugmakers to use tiny radio tracking chips on their product packaging to help thwart counterfeiters.

Drugmakers who follow the guidelines don't have to worry about running afoul of FDA labeling rules, the agency said.

Some drug firms already have plans to use radio frequency identification devices (RFIDs), which will allow them to track products from factory to pharmacy:

- Purdue Pharma, maker of Oxycontin, says it will this week begin shipping bottles of the painkiller with radio antenna chips to Wal-Mart and wholesaler H.D. Smith. Bottles of Oxycontin will be scanned when they get to the warehouses and again when they get to pharmacies.

"If it doesn't scan, it's not ours," says Aaron Graham, vice president and chief security officer for Purdue. The firm is donating 100 devices to law enforcement agencies so they can read chips on any bottles recovered after being stolen.

- Pfizer says it will ship by the end of next year its impotence drug Viagra with the chips embedded in packaging. Viagra is one of the most commonly counterfeited drugs.

- In 12 to 18 months, GlaxoSmithKline says it will pick at least one product for the tracking effort.

The move is part of an effort by the FDA to reduce the counterfeit or adulterated drugs that get into the U.S. supply. In February, the FDA issued voluntary guidelines it says will help drugmakers, wholesalers and retailers curb what is a small but growing problem in the USA. The agency encouraged the drug industry to have RFID in widespread use by 2007.

The jump in counterfeit drug cases — estimated at less than 1% of the total drug supply — is fueled by increasingly sophisticated forged labels, an abundance of small wholesalers buying and selling medication and a growing number of expensive drugs that can net forgers large profits.

In recent years, authorities have seized vials filled with water but labeled as anemia treatment Procrit, bottles of schizophrenia treatment Zyprexa filled with aspirin and pills labeled as Lipitor that were not.

RFID technology isn't inexpensive. The FDA expects cost savings in the long run, but upfront costs for drugmakers, wholesalers and pharmacies could be considerable.

Drugmakers will have to buy the chips as well as tracking technology. Wholesalers and pharmacies will have to buy devices to scan the chips and read the information embedded in them. Such readers can cost thousands of dollars each.

"In order for it to work, everyone up and down the supply chain has to be able to participate," says Myles Culbertson, director for the Product Surety Center at New Mexico State University.

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