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# FDA warns 3 pharmacies making copies of drugs

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By Julie Appleby, USA TODAY

The Food and Drug Administration has warned three large pharmacies that they are violating federal law in making and distributing "thousands of doses" of their own versions of drugs used by asthmatics and others with respiratory illness.

The move addresses what the FDA says is a growing problem: Some pharmacies are mass-producing unapproved copies of brand-name drugs, for no proven medical reason, under less-stringent safety and sterility rules than the agency sets for drugmakers.

Steve Silverman, the FDA's acting assistant director of the office of compliance, says the agency expects the companies to either show they are filling legitimate medical needs or stop mass production.

**STORY:** Safety concerns grow over pharmacy-mixed drugs (March 2005)

Warnings were issued Wednesday to Orlando-based Rotech health care; CCS Medical of Clearwater, Fla.; and Reliant Pharmacy Services, owned by home oxygen company Lincare, which the FDA says has not resolved issues from a December 2004 letter.

Lincare spokesman Joe Grillo said the company had no comment. Rotech did not respond to an inquiry.

Cole Peterson of CCS Medical, a medical-supply company, says the firm was surprised by the warning, saying it was "inconsistent with prior communication" from the FDA. She said the company would work with the FDA and that the medications in question represent less than \$80,000 of the firm's \$400 million annual revenue.

If the companies don't respond satisfactorily, Silverman said they potentially face seizure of their drugs or court actions, such as injunctions, civil or criminal charges.

Pharmacies can make drugs, a process called compounding, when they have legitimate prescriptions for individual patients who require special products not made by commercial manufacturers. Legitimate compounding could include making dye-free products or creating liquid medications for patients who can't swallow pills.

But the FDA says the pharmacies targeted with the warning letters made drugs for patients without proving any unique medical need. The drugs in question are liquids that are poured into devices called nebulizers and inhaled by respiratory patients. Silverman says it is unlikely that patients would receive them from neighborhood pharmacies. Instead, patients may have been attracted to lower-cost drugs advertised on the Internet, or by companies that sell the devices used to inhale the drugs.

USA TODAY highlighted the issue in a March 2005 report that outlined how some patients were switched to pharmacy-made inhalation drugs without their knowledge by pharmacies that profited by substituting their own versions for the brand-name drugs.

Last month, Sen. Charles Grassley, R-Iowa, wrote the FDA and Medicare with concerns about pharmacy-made respiratory drugs. On Thursday, Grassley called the FDA move "a big step in the right direction" and also called on Medicare to tackle the problem.

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The patient-advocacy group Consumer Health Alliance for Safe Medication, which has sought restrictions on compounded asthma drugs, praised the FDA, but said there should be more effort made to notify patients who have received the medications.

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