FDA Warns Three Pharmacies To Stop Mass-Producing Unapproved Inhalation Drugs

The Food and Drug Administration (FDA) has warned three firms, RoTech Healthcare, Inc., CCS Medical, and Reliant Pharmacy Services, to stop manufacturing and distributing thousands of doses of compounded, unapproved inhalation drugs nation-wide. Responsible officials at firms that do not properly address violations identified in FDA warning letters risk further enforcement, including injunctions that prevent further violations and seizure of their products that violate the law.

The three firms warned by FDA say that they produce inhalation drugs as part of the practice of pharmacy compounding. Traditional pharmacy compounding typically involves pharmacies preparing drugs that are not commercially available, such as a unique medicine for a patient who is allergic to an ingredient in a FDA-approved drug. This kind of compounding follows a physician's decision that his or her patient has a special medical need that cannot be met by FDA-approved drugs. FDA normally permits traditional pharmacy compounding and the agency's action is not targeting this practice.

Inhalation drugs are used to treat diseases including asthma, emphysema, bronchitis, and cystic fibrosis. These are potentially life-threatening conditions for which numerous FDA-approved drugs are available. Compounded inhalation drugs may be distributed to patients in multiple states, and patients and their doctors may not know that they are receiving compounded products. FDA urges consumers using inhalation drugs to discuss their medications with their physicians and verify with their pharmacists that the medications they received are what their physicians ordered.

"Compounded inhalation drugs are not reviewed by the FDA for safety and effectiveness, often are not produced according to good drug manufacturing practice, and typically are not sterile. This may expose patients to unnecessary risk," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research. "To avoid these risks, we encourage patients to use FDA-approved drugs whenever possible."

FDA believes that, in compounding mass amounts of inhalation drugs, a number of pharmacies go well beyond traditional compounding. FDA is aware of certain pharmacies compounding millions of doses of inhalation drugs per year. These compounded drugs often simply copy FDA-approved, commercially available drugs, and any differences from FDA-approved drugs do not appear to be related to patients' medical needs. Consumers and health care professionals should notify FDA of any complaints or problems associated with compounded drugs. These reports may be made to MedWatch, FDA's voluntary reporting program, by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm.

Warning Letter to Rotech Healthcare, Inc., Orlando, FL
http://www.fda.gov/foi/warning_letters/g5964d.htm

Warning Letter to CCS Medical, Clearwater, FL
http://www.fda.gov/foi/warning_letters/g5963d.htm

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