FDA alerts health care professionals and patients not to use compounded drugs from Cantrell Drug Company; agency seeks action to stop production and distribution

For Immediate Release

March 1, 2018

Release

The U.S. Food and Drug Administration is alerting health care professionals and patients not to use drug products produced by Cantrell Drug Company of Little Rock, Arkansas, including opioid products and other drugs intended for sterile injection, that were produced by the company and distributed nationwide. The agency is concerned about serious deficiencies in Cantrell's compounding operations, including its processes to ensure quality and sterility assurance that put patient safety at risk. Administration of contaminated or otherwise poor quality drug products can result in serious and life-threatening injury or death.

"A key aspect of the FDA's mission to protect public health is creating a regulatory framework that helps ensure that compounded drugs are made under appropriate quality standards to reduce their risk of patient harm — and to take action when those important standards are forsaken," said FDA Commissioner Scott Gottlieb, M.D. "Despite the FDA's concerns about egregious conditions observed at Cantrell's facility, during several inspections, with the most recent in 2017, the company continued to compound and distribute drugs without adequately addressing their potentially dangerous conditions. This reckless activity threatens patient safety and will not be tolerated."

The FDA has also sought legal action to prevent the company from further producing and distributing drugs. In a preliminary injunction filed today in the U.S. District Court in the Eastern District of Arkansas, the Department of Justice, in conjunction with the FDA, asked the court to order Cantrell to stop manufacturing, processing, packing, labeling, holding and/or distributing any drugs until the company complies with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. The proposed order also will require Cantrell to recall all non-expired drug products on the market.

Products from the company can be identified by looking at the drug labels — which should include the company name, "Cantrell Drug Co." Health care professionals should immediately check their medical supplies, quarantine any drug products from Cantrell Drug Company and not administer them to patients. Examples of some of the drugs that Cantrell has compounded include opioids and common antibiotics. The FDA urges health care professionals who obtained products from Cantrell to make alternative arrangements to obtain medications they administer or dispense to patients from sources that adhere to proper quality standards. Patients who have

received any drug product produced by Cantrell and have concerns should contact their health care professional.

FDA investigators most recently inspected Cantrell's facility in June 2017, and observed poor compounding drug operations. Of particular concern, the FDA investigators observed insanitary conditions and violations of current Good Manufacturing Practice (CGMP) that could cause Cantrell's drugs to become contaminated or made injurious to health. Because Cantrell produces drugs that are intended for sterile injection, the conditions identified — which can expose such products to contamination and render them unsterile — raise significant public health concerns. In response to the FDA's recommendation, in July 2017, Cantrell recalled all drug products marketed as sterile and ceased sterile compounding. However, against FDA advice, the company resumed production and distribution without demonstrating that it had adequately addressed the problems identified.

The FDA is not yet aware of reports of illness associated with the use of Cantrell's products. The FDA asks health care professionals and consumers to report adverse events or quality problems associated with Cantrell Drug Company's products to FDA's MedWatch Adverse Event Reporting program by:

- Completing and submitting the report online at MedWatch Online Voluntary Reporting Form
- Downloading and completing the form, then submitting it via fax at 1-800-FDA-0178

Cantrell is registered as an outsourcing facility under section 503B of the FD&C Act. The Drug Quality and Security Act, signed into law on Nov. 27, 2013, added a new section 503B to the FD&C Act. Under section 503B, a compounder can elect to register as an outsourcing facility.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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