Compounded Drug Products from Cantrell Drug Company: FDA Warning-Serious Deficiencies in Quality and Sterility Assurance

[Posted 03/02/2018]

AUDIENCE: Patient, Health Professional, Risk Manager

ISSUE: FDA 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.

The FDA has also sought legal action to prevent the company from further producing and distributing drugs. In a preliminary injunction filed 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.

BACKGROUND: 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.

RECOMMENDATION: Health care professionals should immediately check their medical supplies, quarantine any drug products from Cantrell Drug Company and not administer them to patients. 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: MedWatch
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[03/01/2018 - News Release - FDA]

Previous MedWatch Alert:

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