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" FDA (2018).

FDA report "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."

Full Alert

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