FDA News Release

Federal court enters consent decree against Ranier's Rx Laboratory and owner for manufacturing purportedly sterile drug products in insanitary conditions

Pennsylvania compounder prohibited from manufacturing and distributing sterile human and animal drug products

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Release

The U.S. District Court for the Western District of Pennsylvania entered a consent decree of permanent injunction today between the United States and Ranier's Rx Laboratory Inc., doing business as Ranier's Compounding Laboratory, of Jeanette, Pennsylvania, and pharmacist Francis H. Ranier, who owns the compounding facility.

"We continue to see concerning activity when it comes to some compounded drugs, including problems related to the conditions under which compounded sterile medicines are made, which can raise significant risks to patients. This is an area of intense focus for the FDA. We're committed to making sure that compounded drugs are made under appropriate production standards and, when necessary, taking enforcement actions against compounders who fail to produce sterile drugs in compliance with the law," said FDA Commissioner Scott Gottlieb, M.D. "Despite our warning, Ranier's and its owner placed patients at risk by compounding purportedly sterile drug products under insanitary conditions. The FDA will continue to pursue enforcement action against companies and owners who place American consumers at risk."

The consent decree prohibits Ranier's and its owner from, among other things, manufacturing, holding, or distributing human or animal sterile drugs compounded at their facility until they comply with the Federal Food, Drug, and Cosmetic (FD&C) Act and FDA regulations.

The complaint filed with the consent decree alleges that Ranier's manufactured and distributed purportedly sterile drug products, including injectable drugs for conditions such as erectile dysfunction and ophthalmic drugs for use as anesthetics, antibiotics, and cataract therapies, among others, that were adulterated under the FD&C Act because the drugs were made under insanitary conditions.

On July 10, 2018, the FDA warned the public against using any human and animal drug products intended to be sterile that were produced by Ranier's due to concerns about the company's ability to assure the sterility of those products. On July 27, 2018, the compounder issued a press release regarding a voluntary recall of all its unexpired sterile compounded drug products.

Under the consent decree, Ranier's and Ranier cannot resume sterile compounding operations for human and animal drugs until they complete required corrective actions and receive authorization from the FDA.

The complaint was filed by the U.S. Department of Justice on behalf of the FDA.

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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