The FDA will take strong action against those who violate the law governing drug compounding; putting patients at risk. Federal judge enters consent decree against outsourcing facility Isomeric Pharmacy Solutions

FDA News Release

Federal judge enters consent decree against outsourcing facility Isomeric Pharmacy Solutions

Compounder manufactured and distributed sterile drug products in violation of law

For Immediate Release

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U.S. District Judge Robert J. Shelby entered a consent decree of permanent injunction yesterday between the United States and Isomeric Pharmacy Solutions of Salt Lake City, Utah, two of the company's co-owners, William O. Richardson and Rachael S. Cruz, and chief operating officer Jeffery D. Brown.

The consent decree prohibits Isomeric, its owners and chief operating officer from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements.

According to the complaint for permanent injunction, Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act. Drugs prepared, packed, or held under insanitary conditions may have been contaminated with filth or otherwise harmful if given to patients. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use.

"Isomeric endangered the public health by manufacturing injectable drugs under poor conditions that compromised their required sterility and put patients at risk," said FDA Commissioner Scott Gottlieb, M.D. "We will continue taking strong enforcement actions against compounders who violate the Drug Quality and Security Act and put patients at risk by failing to produce sterile drugs in compliance with the law."

The FDA most recently inspected Isomeric from Feb. 22 to March 24, 2017. Following the FDA inspection, because of a lack of sterility assurance for its purportedly sterile drug products,

Isomeric agreed to a voluntary nationwide recall of all lots of unexpired drug products produced for sterile use and distributed to patients, providers, hospitals, or clinics nationwide between Oct. 4, 2016 and Feb. 7, 2017.

Previously, the FDA inspected Isomeric in August 2015 and observed similar poor conditions and practices for sterile drug production. Despite assurances that Isomeric was correcting its violations, a follow-up inspection in June 2016 revealed that the company had not implemented adequate corrective actions. Following this inspection, the FDA issued a warning letter to Isomeric.

Isomeric initially registered as an outsourcing facility in July 2015, re-registered in December 2015 and January 2017.

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.