U.S. Food and Drug Administration
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FDA News Release

Federal judge enters consent decree against Downing Labs

Texas compounder manufactured and distributed drug products in violation of law

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Release

On Friday, Jan. 8, U.S. District Judge Sam A. Lindsay entered a consent decree of permanent injunction between the United States and Downing Labs LLC, of Dallas, Texas, and the company's co-owners, Ashley Michelle Downing and Christopher Van Downing, and pharmacist-in-charge, Roger E. Mansfield.

According to the complaint filed with the consent decree, Downing Labs (formerly known as NuVision Pharmacy) manufactured and distributed purportedly sterile drug products that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

"Despite multiple warnings to the company, Downing Labs continued to manufacture injectable drugs under insanitary conditions, putting the health and safety of patients at risk," said Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research. "The FDA pursued appropriate and aggressive action to protect the public health."

The U.S. Department of Justice brought the action on behalf of the FDA. The consent decree prohibits Downing Labs and its owners from manufacturing, holding or distributing drugs until they comply with the FD&C Act and its regulations, in addition to other requirements.

In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products due to a lack of sterility assurance and concerns associated with quality control processes. Prior to the recall, the company received reports that patients had experienced fever, flu-like symptoms, and soreness at the injection site after receiving methylcobalamin injections. In **July 2013 (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM363761.pdf)** and **September 2014 (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM413431.pdf)**, based on findings from the FDA's inspections

ending in **April 2013 (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM348772.pdf)** and **July 2014 (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM405669.pdf)**, the FDA formally requested that Downing Labs recall all of its unexpired sterile products on the market, and warned health care providers and consumers against their use. Downing Labs refused FDA's requests to recall. In June 2015, Downing Labs registered as an **outsourcing facility (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm)**.

Most recently, as a result of serious deficiencies identified by the FDA during an inspection of Downing Labs ending in **October 2015 (http://www.fda.gov/downloads/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom/ucm467321.pdf)**, the company voluntarily conducted a nationwide **recall (http://www.fda.gov/Safety/Recalls/ucm468215.htm)** of its purportedly sterile drug products due to a lack of sterility assurance and ceased sterile operations. The deficiencies included microbial contamination of injectable drug products, inadequate cleaning and sanitization of sterile processing areas, and inadequate sterile practices. FDA investigators also determined that Downing Labs distributed drug products that failed sterility testing.

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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