



Department of Justice

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FOR IMMEDIATE RELEASE
THURSDAY, Oct. 29, 2020
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Nicholasville Compounding Pharmacy and Its Owner Plead Guilty to Unlawful Distribution of Prescription Drugs

FRANKFORT, Ky. –A compounding pharmacy based in Nicholasville, and its owner, admitted on Thursday in federal court to unlawful distribution of compounded prescription drugs.

Tailor Made Compounding LLC (TMC) pleaded guilty to one count of distributing unapproved new drugs throughout the United States, from October 25, 2018 through April 1, 2020, before U.S. District Judge Gregory F. Van Tatenhove. Specifically, TMC pleaded guilty to unlawful distribution of selective androgen receptor modulators (“SARMS”) and other substances that the FDA had not approved for distribution in the United States. SARMS are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. Products containing SARMS were often marketed and sold for body-building purposes. According to the plea agreement, TMC also unlawfully distributed other unapproved new drugs, including BPC 157, Cerebrolysin, CJC 1295, DSIP, Epitalon, GW 501516, Ipamorelin, LGD-4033, LL-37, Melanotan II, MK 677, PEG-MGF, Selank, and Semax. In connection with the plea, TMC agreed to forfeit \$1,788,906.82, representing its 2019 sales for these products.

Jeremy Delk, 40, pleaded guilty to one count of unlawfully engaging in wholesale distribution of a prescription drug, without licensing TMC as a wholesale distributor with the Board of Pharmacy for the Commonwealth of Kentucky. According to the plea agreement, from October 23, 2018 through May 14, 2020, TMC sent 112 vials of Methylcobalamin 10mg/ml 10mL, a prescription form of vitamin B12, to Doctor 1, a licensed physician who operated an anti-aging/wellness clinic in the Greater Los Angeles area. Rather than sending individualized, patient-specific prescriptions to TMC, as is required by law, Doctor 1 made bulk orders of Methylcobalamin 10mg/ml 10mL without issuing prescriptions or providing accurate patient names. Delk, as owner and chief executive officer of TMC, knowingly caused TMC to fill and ship bulk, wholesale distributions of Methylcobalamin to Doctor 1, knowing that TMC had never applied for permission from the Kentucky Board of Pharmacy for TMC to act as a wholesale distributor of prescription drugs. When authorities from the FDA and the Kentucky Board of Pharmacy inspected TMC between August 20 and October 24, 2018, Delk took steps to hide records of TMC’s wholesale distributions of Methylcobalamin, as well as other records.

Tailor Made and Delk were charged by way of information, waiving their right to indictment by a federal grand jury.

“The safety and efficacy of prescription medications is of paramount importance to us all,” said Robert M. Duncan, Jr., United States Attorney for the Eastern District of Kentucky. “When pharmacies intentionally evade the FDA requirements, they are placing their own interests above those of the patients they are supposed to be serving. The community deserves better, and I commend the work of our law enforcement partners in their diligent efforts to protect the public and disrupt this criminal conduct.”

“Compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product. But pharmacies will be held responsible for failing to follow the laws intended to protect patients, including requirements for licensure and limitations on what drugs can be appropriately compounded,” said Special Agent in Charge Mark S. McCormack, FDA Office of Criminal Investigations Metro Washington Field Office. “We will continue to investigate and bring to justice those who put profits above a patient’s health.”

United States Attorney Duncan; Mark S. McCormack, Special Agent in Charge, FDA Office of Criminal Investigations, Metro Washington Field Office; and James Robert Brown, Jr., Special Agent in Charge, Federal Bureau of Investigation jointly announced the guilty plea.

The investigation was conducted by the FDA and the FBI. The United States was represented by Assistant U.S. Attorney Kate K. Smith.

Delk and Tailor Made Compounding are scheduled to be sentenced on February 24, 2021. Delk faces up to 10 years in prison and a maximum fine of \$250,000. However, any sentence will be imposed by the Court, after its consideration of the U.S. Sentencing Guidelines and the applicable federal statutes.

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