NEWS RELEASE

OFFICE OF THE UNITED STATES ATTORNEY
WESTERN DISTRICT OF MISSOURI

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FOR IMMEDIATE RELEASE

Note: Court documents related to today's criminal complaint will be available in .pdf format, and may be downloaded from the district's Web site at www.usdoj.gov/usao/mow.

FLORIDA MAN CHARGED WITH SELLING MORE THAN $1 MILLION OF COUNTERFEIT LIPITOR

KANSAS CITY, Mo. – Todd P. Graves, United States Attorney for the Western District of Missouri, announced that a Florida man was charged in federal court today with selling counterfeit Lipitor, a prescription drug widely used to reduce cholesterol.

Julio Cesar Cruz, 41, of Miami, Fla., was charged in a criminal complaint filed in U.S. District Court in Kansas City, Mo., this morning. **Cruz** is a naturalized U.S. citizen from Cuba.

Today's criminal complaint is part of an investigation of **Cruz** and others relating to the manufacturing, smuggling and distribution in interstate commerce of counterfeit pharmaceuticals that was launched by the Food and Drug Administration in April 2003, Graves said. The investigation also involves the illegal importation, smuggling and distribution of foreign-manufactured, illegally diverted pharmaceuticals. The investigation included, but was not limited to, the prescription drug Lipitor. Lipitor is manufactured and distributed by Pfizer Ireland Pharmaceuticals and Pfizer, Inc.

According to an affidavit filed in support of the criminal complaint, **Cruz** sold 203 bottles of Lipitor 10 mg tablets, with each bottle containing 5,000 tablets, to G&K Pharma LLC, a Florida firm licensed by the state to sell wholesale drugs in Missouri, for $1,368,835. G&K Pharma then sold the Lipitor to Albers Medical Distributors, Inc, a Kansas City firm, for $1,425,060 – a difference of $56,225.

A forensic analysis of those tablets, says the affidavit, confirms that at least some of them

were not manufactured or distributed by Pfizer. The affidavit alleges that every bottle of Lipitor 10 mg tablets purchased by Albers from G&K that has been tested contained at least some counterfeit tablets, i.e., tablets that were not manufactured or distributed by Pfizer. Further forensic analysis confirms that these bottles appear to contain a mixture of counterfeit Lipitor and illegally diverted foreign-manufactured Lipitor commingled together, says the affidavit.

According to the affidavit, a material witness admitted to Food and Drug Administration agents to being personally involved with **Cruz** in a scheme to sell counterfeit and illegally diverted pharmaceutical drugs. This material witness, says the affidavit, confirmed that he/she personally participated with **Cruz** in obtaining illegally diverted foreign manufactured Lipitor, which they illegally smuggled into United States and then sold in this country. This material witness, the affidavit says, further confirmed that he/she personally participated with **Cruz** in a scheme to manufacture counterfeit Lipitor, including the purchase of punches, dies, plates and other items they used to create and manufacture a tablet that appeared to be genuine Lipitor.

"This represents a serious and significant public health concern," Graves said. "Counterfeit drugs entering the U.S. marketplace jeopardize the health of the public because these drugs lack any assurance of safety or effectiveness."

Graves explained that most counterfeit drugs enter the chain of distribution through a secondary "gray market." In most cases, the manufacturer of a pharmaceutical sells the product to a wholesaler, who in turn distributes to retail pharmacies, hospitals, or physicians. "But another market operates outside the normal distribution system," Graves said. Some secondary wholesalers trade among themselves in overstocks, closeout merchandise, drugs nearing their expiration, etc. In those instances, Graves explained, a broker my never actually handle the drugs, but instead trades within the secondary market until the drugs eventually enter the mainstream and are sold to the ultimate user.

Federal law requires wholesale distributors of prescription drugs, other than an authorized distributor of record, to provide to the person who receives the drug a statement identifying each prior sale, purchase, or trade of the drug. "This is commonly referred to as a drug pedigree," Graves said. "This pedigree makes it possible to trace a drug product through the distribution chain."

According to the affidavit, the pedigree for the Lipitor purchased by Albers indicated that G&K Pharma purchased the Lipitor from Pharma Medical LL in Gatlinburg, Tenn., which had purchased it from a Puerto Rican firm, which had itself purchased the drug from another Puerto Rican firm. Bank records for Pharma Medical, says the affidavit, show that the person authorized to transact banking business for Pharma uses the name R.J. Garcia. The affidavit alleges that Garcia is actually a false identity for **Cruz**. According to the affidavit, the Puerto Rican firms listed in the drug pedigree were not actually involved in the distribution.

The 5,000-tablet bottles of Lipitor purchased by Albers were shipped by **Cruz** to Med-Pro, a pharmaceutical repacker in Lexington, Neb. When Med-Pro received the 203 bottles of Lipitor, says the affidavit, they were marked and labeled as having been manufactured by

Warner-Lambert, Ltd., Dublin, Ireland. Pfizer is a division of Warner-Lambert. Albers directed Med-Pro to repackage all 203 bottles into bottles containing 90 tablets each.

According to the affidavit, Albers then sold the 11,299 bottles of Lipitor to H.D. Smith in Wooddale, Ill., for $1,683,551, and directed Med-Pro to ship the bottles. H.D. Smith sold the Lipitor it purchased from Albers in both wholesale and retail markets.

Graves declined further comment on today's criminal complaint, citing an ongoing investigation.

Graves cautioned that the charge contained in the complaint is simply an accusation, and not evidence of guilt. Evidence supporting the charges must be presented to a federal trial jury, whose duty is to determine guilt or innocence.

The case is being prosecuted by Assistant U.S. Attorney Gene Porter. It was investigated by the Office of Criminal Investigations fo the U.S. Food and Drug Administration.

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This news release, as well as additional information about the office of the United States Attorney for the Western District of Missouri, is available on-line at www.usdoj.gov/usao/mow