AFFIDAVIT

I, Stephen M. Holt, Special Agent, Office of Criminal Investigations (OCI), United States Food and Drug Administration (FDA), being first duly sworn, hereby depose and state:

1. I have been a Special Agent with the United States Food and Drug Administration (FDA) Office of Criminal Investigations (OCI), for approximately ten years and am currently assigned to the Kansas City field office. I have been employed as a Federal law enforcement officer for a total of twenty years. In my current position, I conduct investigations involving criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA), Title 21 United States Code, Section 301 et seq., and other federal statutes enforced by the FDA.

2. This affidavit is offered in support of a criminal complaint against Julio Cesar Cruz charging him with the sale of counterfeit drugs. Since April of 2003, I have been involved in a criminal investigation of Cruz and others relating to the manufacturing, smuggling and distribution in interstate commerce of counterfeit pharmaceuticals. The investigation also involves the illegal importation, smuggling and distribution of foreign manufactured illegally "diverted" pharmaceuticals.

3. Title 21, United States Code, Section 321(g)(2) defines "counterfeit drug" to be a drug or the container or labeling of which falsely purports to be the product of, or is falsely represented to have been packed or distributed by, a drug manufacturer, processor, packer or distributor. The sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug is prohibited by Title 21, United States Code, Sections 331(i)(3) and 333(a)(2). However, under Title 21, United States Code, Section 333(c)(5), someone who acts in good faith and has no reason to believe that a drug is a counterfeit drug can assert that as an absolute defense to a prosecution for violating Section 331(i)(3).

4. The FDA is the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs are safe and effective for their intended uses before they may be held and offered for sale to the people of this country. Counterfeit drugs entering the U.S. marketplace jeopardize the health of the American public because these drugs lack any assurance of safety or effectiveness.

5. Safety and efficacy of drugs administered to citizens of this country depends, in part, on maintaining the integrity of the pharmaceutical distribution system. Pharmaceutical distribution in the United States is primarily conducted through a system whereby a manufacturer sells to any one of a number of primary wholesalers who, in turn, distribute to retail pharmacies, hospitals, or physicians. Operating outside the normal distribution system are a number of wholesale distributors participating in what is known as the "grey market". These wholesalers are loosely known as "secondary wholesalers." Secondary wholesalers generally trade among themselves obtaining

overstocks, closeout merchandise, drugs with minimal time left on the expiration period, and other "deals" outside the mainstream distribution system. The secondary marketer is frequently a broker that never physically handles the pharmaceutical. Drugs may be traded multiple times within the secondary market until they enter the mainstream and are sold to the ultimate user. In my experience, the secondary market generally provides the entry point for counterfeit pharmaceuticals to enter the chain of distribution. Because the secondary wholesaler is an opportunistic buyer with price being the determining factor for purchasing a drug product they often, knowingly or not, are the first destination for a counterfeited pharmaceutical drug.

6. Past FDA investigations have revealed that counterfeit drugs are often manufactured and distributed by individuals who have little or no pharmaceutical background or relevant education, and the clandestine nature of the marketing of these drugs makes it difficult, if not impossible, to trace the distribution of the drugs. In 1987, Congress enacted the Prescription Drug Marketing Act (PDMA), which was incorporated into the Food, Drug and Cosmetic Act (FDCA) at 21 U.S.C §§ 331(t), 333(b), and 353(c)-(e). The PDMA 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, including the date of the transaction and the names and addresses of all parties to the transaction (21 U.S.C. § 353(e) (1)). This document is commonly referred to as a drug "pedigree." The failure to provide a pedigree statement is prohibited by 21 U.S.C. § 331(t). In part, Congress' stated intention was to make it possible to trace a drug product through the distribution chain should that become necessary as in the case of counterfeit drugs entering the distribution system.

7. Based on the facts set forth below, there is probable cause that Julio Cesar Cruz has violated Title 21, United States Code, Sections 331(i)(3) and 333(a)(2) (sale of a counterfeit drug). The statements below are based on my personal knowledge, the review of various records and documents obtained and prepared in the course of this investigation, discussions with other law enforcement officers, and the interviews conducted during the course of this investigation. This affidavit does not include each and every fact and detail known concerning this investigation, but instead sets forth only the material facts I believe are necessary to establish probable cause for issuance of a federal complaint and arrest warrant.

FACTS SUPPORTING PROBABLE CAUSE

8. Since April 2003, I have been actively investigating the purchasing, repacking, sale, and distribution of counterfeit prescription pharmaceuticals including, but not limited to, the drug Lipitor. Lipitor is manufactured and distributed by Pfizer Ireland Pharmaceuticals and Pfizer, Inc. (hereafter Pfizer).

9. Through subpoena, I obtained an invoice dated December 9, 2002, and bearing invoice number 2539. Said invoice records the sale by G&K Pharma LLC to Albers

Medical Distributors, Inc. of 203 bottles of Lipitor 10 mg tablets, with each bottle containing 5000 tablets, for a total sales price of $1,425,060.00 (One million four hundred twenty-five thousand sixty dollars). Albers Medical Distributors, Inc., located at 4400 Broadway, Suite 116 and 166A, Kansas City, Missouri, is a pharmaceutical distributor owned and operated by Douglas C. Albers, a registered pharmacist. Also obtained through subpoena is a "Statement Identifying Pharmaceutical Sale" or drug pedigree that pertains to the sale reflected in this invoice. According to the drug pedigree statement, G&K Pharma LLC purchased the Lipitor it sold to Albers Medical Distributors, Inc. from Pharma Medical LLC in Gatlinburg, Tennessee who purchased it from Drogueria Javiness in Puerto Rico who purchased it from J M Blanco in Puerto Rico.

10. There is, in fact, a corporate business entity in Puerto Rico known as J M Blanco. However, interviews of knowledgeable corporate officials and agents of J M Blanco confirm that the company has never sold Lipitor to Drogueria Javiness.

11. There is, in fact, a corporate business entity in Puerto Rico known as Drogueria Javiness. However, interviews of knowledgeable corporate officials and agents of Drogueria Javiness confirm that the company never purchased Lipitor from J M Blanco and never sold Lipitor to either Pharma Medical or G&K Pharma LLC.

12. There is, in fact, a corporate business entity in Gatlinburg, Tennessee, known as Pharma Medical LLC (hereafter Pharma). Pharma opened and maintained a bank account in the Gatlinburg, Tennessee area. Bank records obtained from these accounts show that the person authorized to transact banking business for Pharma uses the name R. J. Garcia. At the time the bank account was opened, the bank obtained a photocopy of the driver's license for R. J. Garcia, which contains a photograph of the person purported to be R. J. Garcia. This photocopy of the driver's license for R. J. Garcia was shown to a United States Probation Officer responsible for the supervision of Julio Cesar Cruz. The United States Probation Officer positively identified the person depicted in the R. J. Garcia driver's license photograph as Julio Cesar Cruz.

13. Julio Cesar Cruz is a convicted felon in both state and federal courts. On or about February 1984, he was sentenced to four years in Florida state prison based on a state court conviction for cocaine trafficking. On or about November 1985, he was released from Florida state prison. On or about May 1995, he was sentenced to 136 months in federal prison based on a federal court conviction for cocaine trafficking. On or about April 2001, he was released from federal prison and began serving a five year term of supervised release. On or about July 2003, he was arrested on both state and federal warrants. The federal warrant alleges he violated the terms of his supervised release. The state warrant alleges that he conspired with Michael Carlow and others to distribute stolen, diluted, illegally diverted, and otherwise bogus pharmaceutical drugs in Florida. Cruz is currently in custody in Florida pending the disposition of these state and federal charges.

14. There is, in fact, a corporate business entity known as G&K Pharma LLC (hereafter G&K). The bank records for G&K show that its bank accounts are controlled by the same Michael Carlow who is accused of having conspired with Julio Cesar Cruz to distribute stolen, diluted, illegally diverted, and otherwise bogus pharmaceutical drugs in Florida. G&K holds a wholesale drug license issued by the State of Missouri that authorizes it to engage in the sale of wholesale drugs in the State of Missouri. Pharma, the company controlled by Julio Cesar Cruz, a/k/a R. J. Garcia, does not hold a wholesale drug license issued by the State of Missouri and is not authorized to engage in the sale of wholesale drugs in the State of Missouri.

15. Based on business records obtained through subpoena, Albers Medical Distributors, Inc., employed Paul Kriger of Calabasas, California as their exclusive agent for the purchase of drugs in the secondary wholesale distribution market. According to a material witness who was interviewed by law enforcement agents in November 2003, and has personal knowledge of the transaction, Paul Kriger, acting on behalf of Albers Medical Distributors, Inc., negotiated with Julio Cesar Cruz, a/k/a R. J. Garcia, for the purchase of the above-described Lipitor from Cruz's company, Pharma. At the conclusion of these negotiations, the parties agreed that Albers Medical Distributors would not purchase the Lipitor directly from Pharma because Pharma did not have a wholesale license for the sale of drugs in Missouri. However, if Pharma first sold the Lipitor to G&K, Albers Medical Distributors could then purchase the Lipitor from G&K because G&K did have a wholesale license for the sale of drugs in Missouri. Julio Cesar Cruz agreed to sell the Lipitor to Albers Medical Distributors through G&K. Even though the paper trail and drug pedigree suggests there was a sale to G&K, the Lipitor was never in the physical possession of G&K and G&K had no role in the sale of the Lipitor other than to act as a conduit through which the Lipitor would be passed from Pharma to Albers Medical Distributors, Inc.

16. I have reviewed bank records associated with the transaction reflected in invoice number 2539 reflecting the sale of Lipitor from G&K to Albers Medical Distributors, Inc. (hereafter Albers). On December 10, 2002, there was a wire transfer from an Albers account in Kansas City, Missouri, to a G&K account in Florida in the amount of $1,425,060.00. On December 11, 2002, there was a wire transfer from the same G&K account to a Pharma account in Tennessee in the amount of $1,368,835.00. The difference between these two amounts is $56,225.00, which is approximately 3.9455 % of $1,425,060.00. There is no corresponding payment from the Pharma account to either Drogueria Javiness in Puerto Rico or J M Blanco in Puerto Rico.

17. According to records obtained through subpoena, the 5000 tablet bottles of 10 mg Lipitor described in invoice number 2539 and purchased by Albers were shipped by Cruz from a location in Florida to Med-Pro, a pharmaceutical repacker in Lexington, Nebraska. Interviews of knowledgeable corporate officials and agents of Med-Pro confirm that R. J. Garcia, a/k/a Julio Cesar Cruz, as well as individuals acting on behalf of Albers communicated to Med-Pro the decision to ship said Lipitor to Med-Pro.

18. When Med-Pro received the 5000 tablet bottles of 10 mg. Lipitor, each of the 203 bottles were marked and labeled as having been manufactured by Warner-Lambert, Ltd., Dublin, Ireland, and bore Lot # 04132V with an expiration date of January 2004. Albers directed Med-Pro to repackage all 203 of the 5,000 count bottles into bottles containing 90 tablets each. When Med-Pro repackaged this Lipitor, the label they affixed to the 90 count bottles listed the Lot # as 04132V 6 and had an expiration date of January 2004. According to Med-Pro officials, the additional number added to the original lot number indicates the number of runs required to complete the repackaging. In this case, the number 6 would indicate it took 6 runs to complete the repackaging. When Med-Pro completed this repackaging process, there were 11,299 bottles containing 90 tablets each.

19. Albers then sold the 11,299 bottles of Lipitor to H. D. Smith in Wooddale, Illinois, and directed Med-Pro to ship the 11,299 bottles to H. D. Smith in Wooddale, Illinois. I have reviewed business records obtained from H. D. Smith that confirm their purchase of this Lipitor from Albers. In particular, there are two separate invoices for the sale of this Lipitor by Albers to H. D. Smith. The first Albers invoice is # 128675, is dated December 12, 2002, and is for 4,662 bottles of 10 mg Lipitor in the amount of $694,638.00. The second Albers invoice is # 128676, is dated December 12, 2002, and is for 6,637 bottles of 10 mg Lipitor in the amount of $988,913.00. The total for these two invoices is 11,299 bottles and $1,683,551.00. I also have reviewed subpoenaed bank records which document these transactions. On December 16, 2002, there was a wire transfer from an H. D. Smith account in Illinois to an Albers account in Kansas City, Missouri in the amount of $1,683,551.00.

20. H. D. Smith sold in the wholesale and retail markets the Lipitor it purchased from Albers that had been repackaged by Med-Pro and bore lot # 04132V 6. The FDA Forensics Laboratory in Cincinnati, Ohio has tested tablets from bottles bearing lot # 04132V 6. Forensic analysis of said tablets confirms that at least some of them were not manufactured or distributed by Pfizer. In fact, every bottle of Lipitor 10 mg purchased by Albers from G&K and repacked by Med-Pro that has been tested has contained at least some counterfeit tablets, i.e., tablets that were not manufactured or distributed by Pfizer. Further forensic analysis confirms that the bottles bearing lot # 04132V 6 appear to contain a mixture of counterfeit Lipitor and illegally diverted foreign manufactured Lipitor commingled together.

21. In November 2003, law enforcement agents, including agents from the FDA, interviewed a material witness in Florida. This material witness admitted that he/she was personally involved with Julio Cesar Cruz in a scheme to sell counterfeit and illegally diverted pharmaceutical drugs. This material witness confirmed that he/she personally participated with Julio Cesar Cruz in obtaining illegally diverted foreign manufactured Lipitor which they illegally smuggled into the United States and then sold within the United States. This material witness further confirmed that he/she personally participated with Julio Cesar Cruz in a scheme to manufacture counterfeit Lipitor, to include the purchase of punches, dies, plates, and other items which they then used to

create and manufacture a tablet that appeared to be genuine Lipitor manufactured by Pfizer.

Under penalty of perjury, I swear that the foregoing is true and correct to the best of my knowledge, information and belief.

/s/ Stephen M. Holt
Stephen M. Holt
Special Agent
U. S. Food & Drug Administration
Office of Criminal Investigations

Subscribed and sworn to before me this 5th day of December, 2003.

/s/ John T. Maughmer
Hon. John T. Maughmer
Chief United States Magistrate Judge