

The Acting Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. Except as specifically noted, the Acting Deputy Administrator adopts, in full, the Opinion and Recommended Ruling of the Administrative Law Judge. Her adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or any failure to mention a matter of fact or law.

Pseudoephedrine is a List I chemical used as a precursor in the clandestine production of methamphetamine. Most clandestine laboratory operators use a variety of methods to conceal their purchases of precursor chemicals and equipment from law enforcement and firms distributing such chemicals and goods are required to carefully scrutinize their sales transactions to prevent the unauthorized purchase and use of such goods. Pseudoephedrine is lawfully marketed in the United States for use as a decongestant in 30 or 60 mg. tablets and the maximum recommended adult daily dose is four 60 mg. tablets per day, amounting to 120 tablets per month. Ephedrine, also a List I chemical which may be used as a precursor in the clandestine manufacture of methamphetamine, is marketed for use as a bronchodilator for asthma and may be used as a topical decongestant.

From 1994 until 1999, DEA clandestine laboratory seizures rose from 263 to 2,025 and in 1999, the national total for all State, local and Federal agencies was 6,835. During an eight-month period in 2000, DEA reported over 3,000 clandestine laboratory seizures. The overwhelming majority of these laboratories were associated with the clandestine manufacture of methamphetamine. Methamphetamine has a high abuse potential and adverse impact on public health. Dependency is the primary motivation for methamphetamine use and between 1993 and 1998, 3,903 methamphetamine-related deaths were reported in the Drug Abuse Warning Network for the Primary Metropolitan and Statistical Areas of San Diego, Los Angeles, San Francisco and Phoenix.

Pseudoephedrine bulk powder is usually imported from China or India, tableted by DEA-registered manufacturers, distributed to various distributors, wholesalers and then to retail outlets. Of DEA's approximately 3,500 chemical registrants in 2000, over 3,100 were distributors. While illegal diversion can occur at any point in the distribution chain, it usually occurs

after the manufacturer has sold its product to a distributor.

OTC's chemical background originated from the business operations of L&M Vending company (L&M Vending), OTC's predecessor entity. On April 30, 1997, Larry Petit filed for a DEA Registration on behalf of L&M Vending. Subsequently, Tim Petit, brother of Larry Petit, filed an Assumed Name Record and Copy Request with the Earl Bullock County Clerk's Office, asserting ownership for the unincorporated business, L&M Vending. Articles of Incorporation for L&M Vending were later issued by the Office of Secretary of State of Texas, naming "Larry Petit," "Mitzi Petit," and "Timmy Petit" as initial directors of the corporation. Larry Petit was designated the initiated Registered Agent for L&M Vending.

By letter of November 15, 1999, OTC informed the DEA that, effective August 1, 1999, L&M Vending no longer sold List I chemical products, L&M Vending surrendered its DEA Certificate of Registration and transferred to OTC, via invoice, all of its inventory of products containing List I chemicals. Larry Petit, who had performed confidential informant work for DEA in which L&M Vending was used, testified at the hearing that OTC was formed in order to shift legitimate List I chemical products sales away from L&M Vending's informant operations. Due to policy changes within the agency, DEA discontinued using Larry Petit applied as a cooperating source in September of 1997. In May of 2001, L&M Vending was still in business, supplying novelty merchandise to convenience stores.

Larry Petit testified during the hearing in this matter that Tim Petit was the owner of L&M Vending and OTC. However, on June 30, 2000, after these proceedings began, OTC filed Articles of Incorporation with the Texas Secretary of State, listing Larry Petit, Mitzi Petit and Timmy Petit as directors of the corporation. On May 5, 1999, Tom Petit applied for a DEA Registration for OTC to distribute List I chemical products. In connection with OTC's May 5, 1999, application for a DEA Registration, on July 30, 1999, DEA and Larry Petit (on behalf of OTC), entered into a Memorandum of Agreement ("MOA"). In the MOA DEA promised to grant OTC a Certificate of Registration for chemical code numbers 8112 (pseudoephedrine), 8113 (ephedrine) and 1225 (phenylpropanolamine), in exchange for Respondent's compliance with requirements beyond those stated in Federal, State and local law. Generally, the Respondent agreed to maintain complete records, review each sale for

any suspicious transaction, identify its customers and promptly notify DEA in the event of a change in business or ownership.

A DEA registration was issued to OTC on or about July 30, 1999, and was scheduled to expire December 31, 2000, if no renewal application was filed. OTC was thus authorized to distribute List I chemical products while its registration was valid, until July 17, 2000, when the Administrator entered his Order of Immediate Suspension of Registration.

On December 22, 2000, Tim Petit filed a renewal application for DEA registration. The application was "OTC Distribution.Co." typed in as the registrant's name. However, handwritten below that entry was "OTC Distribution Inc." Additionally, in the explanation section of the application, the words "Temporary (sic.) Suspended" were handwritten. Tim Petit signed the renewal application, designating himself as "President-Owner" of the business. On August 31, 2000, OTC filed a Designation of Representatives and Power of Attorney (Designation), pursuant to 21 CFR 1316.50. The Designation, executed by Tim Petit, appointed Larry Petit "as representative of the sole proprietorship and/or Corporation, *nunc pro tunc* to July 7, 1999 (for the proprietorship) and June 30, 2000 (for the Corporation), to represent either or both with regard to matters within DEA's jurisdiction." While Larry Petit provided testimony on behalf of the Respondent, Tim Petit did not appear or testify at the hearing.

Both L&M Vending, Inc. and OTC conducted business through "800" numbers on vehicle cell phones. L&M Vending is not listed in the Dallas area telephone directory. Larry Petit testified at the hearing that he did not know whether or not OTC was listed in the telephone directory. Testimony at the hearing also established that OTC had never had a marketing plan, never advertised, had promotions, nor provided point-of-sale advertising. Larry Petit did not know the number of pseudoephedrine tablets sold in 2000, had not assessed the total market for that product, was unaware of his market share for that product and did not have a product catalogue or price list.

In the Memorandum of Agreement which OTC entered into with DEA in 1999 in order to become registered, the company agreed to maintain records of receipt, distribution and returns of each transaction of listed chemical products, even if the transaction was not a regulated transaction. These records were to include information as to the purchaser's identity, date of transaction, full description of the product and