controlled substances after his DEA registration had expired.

The Acting Deputy Administrator will now consider the factors used by DEA to determine the public interest. Under 21 U.S.C. 823(f), the Attorney General shall register a practitioner to handle controlled substances unless the Attorney General determines that the registration of the applicant is inconsistent with public interest.[2] In determining the public interest, the Acting Deputy Administrator shall consider:

1. Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

2. Compliance by the applicant with applicable Federal, State, and local laws;

3. Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or the chemicals controlled under Federal or State law;

4. Any past experience of the applicant in the manufacture and distribution of chemicals, and

5. Such other factors as are relevant to and consistent with the public health and safety.

Consideration of the first factor weights heavily against Respondent. Respondent could not account for a large amount of Demerol that had been purchased by the MediCenter. Respondent never audited his supplies of controlled substances and at the hearing testified that he was not even aware of the existence of the Code of Federal Regulations.

With regard to the second factor, there was substantial evidence that Respondent failed to comply with Federal, State and local law. His diversion of Demerol for his own use violated 21 U.S.C. 841(a). His failure to conduct audits of the controlled substances in his place of business violated 21 U.S.C. 827. Respondent's issuance of prescriptions to himself and his wife under other doctors' names violated 21 U.S.C. 841(a) and 21 CFR 1306.04 and 1306.05.

As for the third factor, there is no evidence that Respondent had any prior convictions related to controlled substances. The fourth factor is not relevant to these proceedings.

With regard to the fifth factor, many considerations weigh heavily against providing Respondent with a DEA Certificate of Registration. Respondent's misconduct is extremely alarming. The diversion of Demerol for his own use and his long-term issuance of prescriptions for controlled substances in other physicians' names are particularly disturbing. Moreover, even in the face of overwhelming evidence of his misconduct, Respondent has failed to admit to any intentional misconduct whatsoever. Respondent's appalling misconduct and his continued denials about his misuse of controlled substances show that he has failed to recognize the gravity of his actions and that it would not be in the public interest to permit him to handle controlled substances. Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100 and 0.104, hereby finds that the performance of the evidence establishes that the registration of Respondent as a practitioner would be inconsistent with the public interest.

Therefore the Acting Deputy Administrator hereby orders that Respondent's application for a DEA Certificate of Registration and any requests for renewal or modification submitted by Respondent be, and hereby are, denied.

Dated: November 26, 2003.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 03–31218 Filed 12–17–03; 8:45 am]

BILLING CODE 4410–09–M

[2] This function has been redelegated to the Acting Deputy Administrator of DEA.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 00–22]

OTC Distribution Company; Revocation of Registration

On May 9, 2000, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to OTC Distribution Company (''OTC'') as to why the OTC's DEA Certificate of Registration as a distributor of List I chemical products should not be revoked as being inconsistent with the public interest, as determined by 21 U.S.C. 823(h). The Order to Show Cause alleged that: (1) OTC (Respondent) had failed to comply with the terms and conditions agreed to in a Memorandum of Agreement (MOA) with the DEA, including the requirements: To abide by all laws relative to listed chemicals, to report all sales and purchases to DEA monthly, to prepare quarterly inventories, to contact the DEA field office regarding questions about potential customers and to institute effective control and procedures against diversion; (2) multiple bottles of OTC pseudoephedrine were seized from an illicit manufacturing lab in Oregon; (3) OTC failed to report an uncommon method of payment as required by 21 CFR 1310.05(a); (4) OTC shipped listed chemicals to an unregistered location in violation of the MOA; (5) an audit of OTC's purchase orders and sales invoices revealed a failure to comply with the regulatory requirements of 21 CFR 1310.06(a); (6) the audit also revealed that OTC was unable to account for approximately 415,000 bottles of pseudoephedrine as a result of a failure to maintain complete and accurate records; and (7) the monthly sales spreadsheets OTC provided to the DEA underreported the company's actual total pseudoephedrine sales by more than 200,000 bottles.

By letter dated June 6, 2000, Respondent, by counsel, filed a request for a hearing on the issues raised by the Order to Show Cause and the matter was docketed before Administrative Law Judge Gail A. Randall. On July 17, 2000, the Administrator of the DEA issued an Order of Immediate Suspension of Registration based on the fact that: (1) After the Order to Show Cause was issued, a second audit of OTC's inventory and records revealed a shortage of over 10,000 bottles of pseudoephedrine; and (2) subsequent to the issuance of the Order to Show Cause, the DEA sent four warning letters to the Respondent, alleging that OTC's pseudoephedrine products had been found at various sites related to the illegal manufacturing of methamphetamine.

Following prehearing procedures, a hearing was held in Arlington, Virginia on September 5–6, 2000, and in Dallas, Texas on November 15–17 and December 5–7, 2000, and on May 8, 2001. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted Proposed Findings of Fact, Conclusions of Law and Argument. On August 8, 2002, Judge Randall issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Opinion and Recommended Ruling), recommending that Respondent's DEA registration be revoked. Both parties filed exceptions to the Opinion and Recommended Ruling and on September 27, 2002, Judge Randall transmitted the record of these proceedings to the Deputy Administrator.

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'c 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

method of transfer and the method of payment. Receipt and distribution records were to be maintained at the registered location or at Larry Petit's daughter-in-law's, Tita Petit's, office, be readily retrievable and maintained for two (2) years after the transaction. Distribution of all List I chemical products were to be made under the name OTC.

Larry Petit further agreed to mail photocopies of receipt and distribution records of listed chemical products to DEA on a monthly basis and submit monthly reports to DEA of mail order sales of listed chemical products. OTC was not in compliance with the MOA because OTC failed to regularly provide the requisite purchase records to DEA for its listed chemical products. OTC also failed to provide DEA with monthly purchase records, although it did provide monthly sales records. Both were required by the MOA.

Respondent also agreed in the MOA that Larry Petit would personally review each sale by OTC of listed chemical products for suspicious orders, any and all of which were to be promptly reported to DEA. Although not required of List I chemical distributors by law, under the MOA, Respondent was obligated to take quarterly inventories of its List I chemical products, which would include the List I chemical's name, strength, form of packaging, amount in stock, date of inventory and a witnessed signature of the person taking the inventory.

OTC was also required to keep two forms of identification on file for all customers and maintain a separate file on each customer purchasing List I chemical products. For retail customers, the file should include a copy of the customer's business license and photographs of the establishment bearing the company name. If the company was a DEA registrant, that status was to be verified with the DEA Dallas Field Division. OTC was also to ensure the ''ship to'' address of retail customers matched the addresses on business licenses maintained in the customer files.

OTC's List I chemical products were to be received and stored only at 12617 Gaslite Drive, Dallas, Texas and DEA approval was required before OTC could use any other storage facility. OTC also agreed to provide advance notification to the Dallas Field Division of any planned ownership change in OTC and promptly notify DEA if OTC Distribution Co. discontinued business.

During a pre-registration investigation of Respondent's premises conducted July 28, 1999, DEA Investigators reviewed the terms of the proposed MOA point by point with Larry Petit, who was permitted to ask questions and make comments on the terms of the agreement. Larry Petit did suggest some changes and DEA agreed to allow OTC's books to be kept at Tita Petit's residence, separate from OTC's registered location. Larry Petit was advised that he would have to very carefully and fully identify OTC's customers and comply with regulations stipulated in the Code of Federal Regulations. Copies of regulations and warning sheets, advising the DEA had seized combination ephedrine and pseudoephedrine at clandestine methamphetamine laboratories, were also provided. Larry Petit was instructed that OTC should have a photocopy of customer's applications or DEA licenses or of photographic identification or driver's licenses and should physically verify that the company existed.

The Acting Deputy Administrator agrees with the Administrative Law Judge that this MOA is a valid and binding agreement between DEA and Respondent.

On March 30, 2000, DEA Diversion Investigators went to Tita Petit's residence. Since August 1999, Tina Petit had worked for OTC, assisting Larry Petit in keeping the company's List I chemical product records, and the records were maintained at her residence. The Diversion Investigators asked for OTC's purchase and sales records, and Tita Petit produced hardcopy sale and purchase invoices which she confirmed were ''all the records.'' The records were found to be incomplete in that they did not indicate when and if a product was actually received. Tita Petit indicated she and Larry Petit were trying to ''work out the problem'' and at that time there was no real way to tell when a shipment had been received. During this period they were working with OTC's main supplier of List I chemical products, OTC Brokerage, Inc. (''OTCB''), to match up invoices. In a May 10, 2000, letter to DEA, Larry Petit indicated OTCB had not provided OTC with complete purchase records.

The Diversion Investigators attempted to conduct an audit of the company's List I chemical products. The audit covered the period July 30, 1999, to March 30, 2000. In addition to the incomplete receiving records, the Diversion Investigators found inconsistencies in the sales records. The Investigators went to some of OTC's suppliers in an attempt to determine exactly how much product was received by OTC during the audit period. They were not able to obtain all the information they needed. The audit disclosed shortages of several products including thousands of bottles of pseudoephedrine.

Diversion Investigators conducted another inspection on May 23, 2000. They inventoried approximately 1,500 bottles of List I chemical products on hand, a figure Larry Petit certified. Using Respondent's list of sales of the month of May 2000 and purchase and sales documents from OTC, and two of its suppliers for that month, DEA personnel determined that for the month of May 2000, OTC had additional shortages of 10,589 bottles of List I chemical products.

The Administrative Law Judge found that as a chemical registrant, OTC had an obligation to maintain records regarding List I chemical products and to keep purchasing records and sales records. Further, pursuant to paragraph 7 of the MOA, OTC was required to keep an inventory of all List I chemicals on a quarterly basis. Pursuant to the MOA, OTC was also required to keep sales invoices. The sales invoices DEA obtained March 30, 1999, were retained pursuant to that requirement, but those records were incomplete. More than half of the 179 invoices (98) did not denote the method of transfer, which should be recorded in accordance with DEA regulations. The MOA also required recordation of the method of payment, yet approximately 56 or 57 of the total invoices reviewed failed to note method of payment.

In the months following its pre-registration inspection, OTC provided DEA with sales records in accordance with the MOA, but not the required purchase records. The purchase records were, however, promptly produced in January or February 2000 after they were requested.

Between July 1999 and February 2000, Koehn Enterprises of Texarkana, Texas purchased 600 cases of pseudoephedrine product from OTC. On February 15, 2000, a DEA Diversion Investigator went to the location that OTC shipped to and found Koehn's registered location to be a day care center and that its List I chemical products were being stored at another unregistered address. Koehn also had been arrested on state charges for unlawful transfer of precursor chemicals. DEA was advised that Koehn made many shipments of List I chemicals to Las Vegas, Nevada to customers taken over from OTC. Koehn was unable to account for 97 cases of pseudoephedrine which it had received from OTC.

OTC was also receiving, processing and distributing orders containing List I chemical products at the AIT Freight

facility. When an air shipment came into AIT, OTC's salesman would come to the facility and break down the shipment into orders. While some would be given to AIT for re-shipment, others would be given by OTC's salesman to customers who came to AIT's dock. On May 12, 2000, the salesman was seen supervising the loading of apparent pseudoephedrine product into a rental truck, which then left the area. Thus it appeared that OTC was shipping or distributing List I chemicals from an unregistered location.

From April to June 2000, Respondent kept an organized chart of pseudoephedrine product activity. This chart included: Detailed information as to customers' identity and addresses, DEA registration numbers, dates of request, invoice numbers, types of carrier used to deliver the product, quantities of product sold, any amounts returned, OTC purchase order numbers, the customers' purchase order numbers, specific product information and the payment numbers.

With regard to customer compliance, OTC sent a packet of information to its customers containing information about reporting suspicious orders, complying with DEA regulations and restricting terms of resale. It also sent a contract to retailers selling OTC products which required implementing and educating store employees on a ''maximum purchase policy'' and compliance with all DEA regulations. OTC also sent a conditions of sales contract to its distributor customers, explaining its requirements for resale of pseudoephedrine and ephedrine products. A suspicious orders guide sheet was also provided both retail and distributor customers, enumerating a list of suspicious factors found in the DEA's Chemical Handler's Manual. It also explained that distributors, who were most familiar with their customers and circumstances, must use their best judgment in identifying suspicious orders. Govt. Ex. 11 at 5. With regard to OTC's customer files, most contained photographs of their facilities and photocopies of their representative's driver's license.

OTC reported suspicious transactions to DEA by letter five times between November 18, 1999, and June 22, 2000. Its predecessor, L&M Vending, also reported suspicious transactions by letter on five occasions between March and July 1999.

DEA has implemented a system of documenting and informing a company that products it has manufactured or distributed have surfaced at a site associated with clandestine drug manufacturing. Fourteen DEA Warning Letters were addressed to Respondent between January 6, 1999, and October 18, 2000, enumerating over 20 different seizures of OTC's pseudoephedrine product at clandestine sites. These letters documented the seizure of 28,423 bottles of 60-count List I chemical product, 116 bottles of 100-count List I chemical product and 32,589 bottles of 120-count List I chemical products. During the period November 1999 to July 2000, OTC pseudoephedrine product was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone.

OTC sold List I chemical products to Tobacco Wholesale. Sales increased from 110 cases in February 2000 to over 800 cases by May 2000. Larry Petit thought this was appropriate, as that firm would become OTC's regional distributor in Oklahoma. He also testified he had an agreement with another List I chemical wholesaler, Branex to be OTC's regional distributor in Florida. However, this was not a written agreement, but one orally negotiated by OTC's salesman. Petit was unaware if OTC had a special price agreement with Branex, whether he had assessed Branex's ability to compete in the Florida pseudoephedrine market or if Branex had been asked to provide OTC a list of its retail customers.

There were instances when Larry Petit also did not check on the trade references supplied by customers or know if anyone from OTC had checked on their downstream customers. Petit also admitted that he ignored references supplied by customers even though he referred to the reference as a ''bad guy.''

In the traditional market, Pfizer is the manufacturer and distributor of the Sudafed product line and one of the largest sellers of pseudoephedrine products in the United States. Pfizer's major customers include retail trade outlets such as drug and grocery store chains and mass merchandisers. From August 1999 to April 2000, OTC sold almost one-third the number of pseudoephedrine products sold by Pfizer nationwide. Pfizer's representative was not aware of OTC as a competitor and concluded OTC's brand was not sold in the same market as Sudafed.

The L. Perrigo Company is the largest manufacturer of over-the-counter pharmaceutical products for the ''store brand'' market, which are sold under various labels and compete with nationally advertised brands. From August 1999 until April 2000, OTC sold over one-third the number of tablets of pseudoephedrine product sold by Perrigo. Perrigo's representative had never seen or heard of the OTC's product and concluded it was neither a national brand nor a competitor of Perrigo's.

During the hearing and in post-hearing filings, the Government asserted that Respondent's registration should be revoked on public interest grounds. It argued that OTC failed to maintain effective controls against diversion, that the MOA bound OTC to additional requirements with which OTC failed to comply and that OTC failed to take corrective action after being notified of possible diversion of its product. The Government also contends OTC failed to comply with relevant Federal, State and local law by failing to report a regulated transaction which included a suspicious method of payment to DEA, failure to identify the other party to a regulated transaction, failure to keep and maintain records of regulated transactions and failure to keep and maintain accurate inventory records.

The Government contends OTC's principal manager was aware of DEA regulatory requirements and knew, through DEA Warning Letters, that its pseudoephedrine product was being diverted to the illicit production of methamphetamine. The Government further argues OTC was not providing listed chemical products for the traditional and recognized therapeutic market.

Respondent contends it substantially satisfied its regulatory obligations, entered into a voluntary agreement imposing additional responsibilities, substantially followed those obligations and attempted to consult with DEA to improve its operations. It further points to Larry Petit's extensive work with the DEA. While acknowledging violation of the record-reporting provision of the MOA when it failed to provide purchase orders to DEA, it argues this violation does not justify revocation, given OTC's remedial efforts to rectify that error.

Pursuant to 21 U.S.C. 823(h) and 824(a)(4), the Acting Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal for such registration, if she determines that registrant's continued registration would be inconsistent with the public interest. Section 823(h) requires that the following factors be considered in determining the public interest:

(1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels.

(2) Compliance by the applicant with applicable Federal, State and local law.

(3) Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law.

(4) Any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) Such other factors as are relevant to and consistent with the public health and safety.

These factors are to be considered in the disjunctive; the Acting Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied *See Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

As a preliminary matter, the Administrative Law Judge refused the Government's request to take official notice that ''no business entity, intended to be a going concern, operates in such a fashion as OTC did.'' The Acting Deputy Administrator agrees that the broad assertion of OTC's illegitimacy as an on-going business entity embodied in this particular request is not appropriate for official notice. However, the Acting Deputy Administrator disagrees with the Administrative Law Judge's broad conclusion that DEA possesses ''no specialized knowledge pertaining to general business practices of legitimate business entities'' (ALJ Decision at 47). The DEA does possess special expertise in many areas of business operations, both legitimate and illegitimate, which relate to the manufacture and distribution of controlled substances and List I chemicals.

Nevertheless, deciding whether or not ''any'' business entity, intending to be an ongoing concern, would operate as OTC did, does require a qualitative analysis of the evidence in the particular record on a finding which could materially impact the outcome. The request also does not involve an ''obvious and notorious'' fact (*See* Attorney General's Manual at 79), is open to dispute and is not capable of ready and certain verification. Considering the foregoing and the scope of the request, the Acting Deputy Administrator will not take official notice of the specific fact which was requested.

Nevertheless, certain facts established in the record do indicate numerous deviations from what would be considered sound business practices of companies engaged in distributing regulated chemicals. As did the Administrative Law Judge, these facts will be considered by the Acting Deputy Administrator in determining the public interest in OTC's continued registration.

The Acting Deputy Administrator also agrees with the Administrative Law Judge that OTC Distribution Company's Certificate of Registration was not terminated as a matter of law when, after initiation of these proceedings, Tim Petit filed Articles of Incorporation with the State of Texas in the name of ''OTC Distribution, Inc.'' Ambiguity as to the Respondent's intent to alter its status as a sole proprietorship to that of corporation and to use a renewed certificate to carry out its business, was generated by conflicting notations on the December 22, 2000, application for renewal of registration signed by Tim Petit.

However, no requests for a modification to change the registrant's name or transfer the certificate of registration to a new corporate entity were ever submitted. The Government also did not introduce evidence of conduct by OTC Distribution Co., consistent with a conclusion that OTC Distribution Co. had ceased existence or discontinued business. Neither was any Texas law offered to support the conclusion that, by operation of law, OTC Distribution Co. ceased legal existence or discontinued business, simply upon filing of the articles of incorporation. Accordingly, the Acting Deputy Administrator agrees with the Administrative Law Judge that OTC Distribution Company's DEA Certificate of Registration remains a viable, if temporarily suspended, registration whose fate cannot be decided by summary disposition.

With respect to factor one, maintenance of effective controls against diversion, the Acting Deputy Administrator agrees with the Administrative Law Judge that Respondent's physical storage facility met or exceeded minimum security requirements. However, while physical security is a focus of 21 CFR 1309.71 (2000), the Acting Deputy Administrator agrees with the Government's exception to the Opinion and Recommended Ruling, that the Administrative Law Judge's discussion on this factor was unnecessarily limited to the adequacy of storage and physical access to Respondent's List I chemical products.

Among the factors required to be considered by the Acting Deputy Administrator under the general security requirements of 21 CFR 1309.71, is ''[t]he adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution and disposition of List I chemicals in its operations.'' 21 CFR 1309.71(b)(8). Further, prior agency rulings have applied a more expansive view of factor one than mere physical security. *See, e.g., Alfred Khalily, Inc.*, 64 FR 31,289, 31,292 (1999) and *NVE Pharmaceuticals, Inc.,* 64 FR 59,215, 59,217–18 (1999) (failure to identify a party to a transaction or engaging in transactions with non-registered entities fell under factor one); *State Petroleum, Inc.*, 67 FR 9,994, 9,994 (2002); *Hadid International, Inc.*, 67 FR 10,230, 10,231 (2002) and *Aqui Enterprises*, 67 FR 12,576, 12,578 (2002) (recordkeeping inadequate to track sales and customers within factor one).

Respondent's failure to maintain adequate administrative records and controls to permit a more precise audit of its List I chemical products, its inability or unwillingness to fully comply with its record keeping and report obligations under the MOA, its distribution of List I chemical products directly to customers from a freight facility loading dock and substantial seizures of OTC pseudoephedrine products from illicit sites, all weigh against Respondent as to factor one.

With regard to factor two, compliance with applicable law, the Acting Deputy Administrator agrees with the Administrative Law Judge that OTC was bound to comply with the provisions of the MOA, in addition to the recordkeeping, reporting and identification requirements in the Code of Federal Regulations. OTC then failed to provide the DEA with adequate inventory records, complete sales invoices or with any purchase records.

With regard to the accountability audits conducted by DEA Diversion Investigators which resulted in their finding of overages and shortages of listed chemicals, Respondent has filed exceptions to the Opinion and Recommended Ruling of the Administrative Law Judge. OTC argues the audits were not undertaken in a ''manner that lends credibility to their results'' and ''were based on erroneous assumptions.'' Respondent's Exceptions at 4. However, the inability of DEA personnel to precisely account for the receipt and distribution of OTC's List I chemical products was principally attributable to Respondent's failure to maintain adequate records. The Acting Deputy Administrator is particularly troubled that Respondent was placed on notice by the terms of the MOA as to its need to maintain accountability for the List I chemicals it distributed—through its own records—and nevertheless failed to fully comply with those requirements either by intent, ignorance or neglect.

There was a substantial deviation between the results of two investigators

as to the number of unaccounted for bottles from the audit. Nevertheless, using the smaller numbers, the Administrative Law Judge characterized OTC's unaccounted for product as being ''unacceptably large.'' However, in its exceptions, Respondent points to the inability of OTC's supplier, OTCB, to provide exact figures as to the amount of product it shipped to OTC during the audit period, thus degrading the reliability of the figures the Diversion Investigator was required to use in making her calculations. The Administrative Law Judge adequately acknowledged the inherent difficulty in arriving at a bottom line using the records that were available. It also should be noted that OTC was required to maintain complete records of all listed chemicals it received. Nevertheless, given the large figures of unaccounted for product, it was reasonable to infer that even given the problems in accuracy noted in the record here, there were still unacceptably large quantities of unaccounted for List I chemical products in OTC's records. Further, the gravaman of the Administrative Law Judge's opinion in this section was OTC's internal failure to maintain adequate records. The Acting Deputy Administrator agrees and concludes that failure is significant and contributes to the risk to the public interest of OTC's chemical products being diverted to the illicit market. *See, e.g., In the Matter of David N. Pruitt,* 57 FR 11,339, 11,340 (1992).

Based on inclusion of the unregulated product Maxinol, in the computation chart prepared by one of the Diversion Investigators based on OTCB records (Govt. Ex. 95) and photographs of that product taken during the May 23, 2000, inspection, Respondent's exceptions further challenge the overall validity of the audits. However, it was jointly stipulated by the parties that Maxinol does not contain a List I chemical and the Administrative Law Judge's findings relating to that audit and her decision were not premised on the apparent 1296 unaccounted for bottles of Maxinol. Indeed, the six other products in the computation chart which did form the basis for the judge's findings regarding the audit, are all products containing List I chemicals and reflect large quantities of unaccounted pseudoephedrine product, including a shortage of 54,403 bottles of OTC's 120-count 60 mg. product. The Acting Deputy Administrator finds Respondent's exception to be without merit.

The Administrative Law Judge concluded Respondent engaged in suspicious regulated transactions involving uncommon methods of delivery and payment. Such transactions are required to be reported to the DEA pursuant to 21 CFR 1310.05(a)(1) (2000). With regard to delivery, OTC representatives received, processed and distributed orders containing List I chemical products directly from a freight facility, an unregistered location. These transactions would be regarded as suspicious transactions. However, the Acting Deputy Administrator agrees with the Administrative Law Judge that there was insufficient evidence showing Respondent shipped List I chemical products to an unregistered location in connection with sales to Worldwide Wholesale.

The Administrative Law Judge found OTC engaged in a suspicious, unreported transaction when it accepted $70,000.00 in cash from T.J. Wholesale as part of a transaction for products containing List I chemicals. Noting the finding that Larry Petit did not think the payment suspicious, Respondent has filed an exception asserting the Administrative Law Judge's decision in effect, improperly places the characterization as to what constitutes a ''suspicious order in the hands of the Agency after the fact.''

While the seizure of pseudoephedrine, sold by OTC to T.J. Wholesale and later discovered in illicit laboratories, had not yet been reported to OTC by a Warning Letter, the suspicious circumstances of the cash transaction were readily apparent to any reasonable person. Larry Petit's explanation, that he did not think it unusual for someone going to Las Vegas to have $70,000.00 cash, begs the relevant question. While perhaps a ''big-time'' gambler might carry cash for that purpose, that does not explain why a legitimate business enterprise would purchase a substantial amount of List I chemical products with cash, let alone $70,000.00 worth of pseudoephedrine.

In addition to the testimony of a Diversion Supervisor that payment in cash is suspicious, payment in cash and by cashier's check were identified as reasons to consider a particular transaction as being suspicious in the very materials OTC sent its own customers. OTC also included cash payments as suspicious in proposed conditions of sale contracts with its customers. (*See* Govt. Ex 11 at 4.) That Larry Petit recognized the unusual nature of the transaction was also indicated by his testimony that he told T.J. Wholesale's representative that he would take the cash ''one time only'' and ''I don't operate my company that way.'' (Tr. at 1295.) Given the foregoing, the Acting Deputy Administrator concludes Larry Petit recognized the unusual nature of this transaction and it should have been reported to DEA at the time.

The Administrative Law Judge found OTC engaged in over-the-threshold regulated transactions of pseudoephedrine products with a non-registrant. (Finding of fact 47.) This involves sales to the Red Coleman Stores. Respondent filed exceptions to this finding, arguing Red Coleman is a retail distributor which did not have to be registered with DEA. The Acting Deputy Administrator agrees the evidence is ambiguous on this point and insufficient to show the Red Coleman Stores engaged in over-the-threshold retail transactions requiring that company's registration. Accordingly, the Administrative Law Judge's finding of sales to a non-registrant in violation of DEA regulations will not be adopted.

Regarding factor three, relevant conviction record, the Administrative Law Judge found that neither the Respondent nor its principal officers have any prior conviction record relevant to the handling of List I chemicals.

Regarding factor four, applicant's experience in distributing chemicals, the Administrative Law Judge found that the officers of OTC and Larry Petit in particular, had extensive experience with distributing List I chemicals, much of which stemmed from the operation of L&M Vending Company and Larry Petit's work with DEA.

With respect to factor five, such other factors relevant to and consistent with public health and safety, the Administrative Law Judge noted the serious impact upon the public interest of the diversion of List I chemical products into the illicit production of methamphetamine. Acknowledging the distinction between ''Traditional'' and ''Non-Traditional'' markets, the Administrative Law Judge concluded OTC engaged in unusual business practices, raising suspicions as to the exact source of OTC's customer base and intended purpose of its business operations.

Specifically, OTC was not listed in the Dallas area telephone directory, did not have a marketing plan during its formation and early days of operation, has no product catalog or price list, never engaged in promotions or advertising and had no employees. Additionally, Larry Petit did not know OTC's market share of List I chemical products. However, the evidence showed OTC sold over 92 million tablets of pseudoephedrine product

from August 1999 until April 2000. This is a sizable share compared to the sales of the two largest sellers of pharmaceutical pseudoephedrine products in the United States, Pfizer and Perrigo. Despite the ''share'' of the potential market that OTC's millions of tablets represented, neither the Pfizer or Perrigo representatives were even aware of OTC as a possible competitor.

Further, the government established that between January 6, 1999 and October 18, 2000, 14 Warning Letters enumerated over 20 different seizures of OTC's pseudoephedrine products from illicit sites, including 28,423 bottles of 60-count product, 116 bottles of 100-count product and 32,589 bottles of 120-count products. The Acting Deputy Administrator agrees with the Administrative Law Judge that these warning letters demonstrate the movement of OTC's List I chemical products into the illicit market, an additional factor that OTC's continued handling of these products creates a risk to the public health and safety by fueling the activities of that illicit market.

The Acting Deputy Administrator has considered the totality of the circumstances, including Respondent's favorable evidence. *Martha Hernandez, M.D.,* 62 FR 61,145, 61,147 (1997). In this regard, Larry Petit's relationship with DEA as a cooperating source; OTC's financial audit and efforts undertaken to improve the company's financial records and better monitor its billing and shipping records and invoices; OTC's willingness to take action in response to several DEA Warning Letters; its acceptable customer compliance files; and the filing of some suspicious transaction reports by OTC are all noted. The Acting Deputy Administrator has also taken into consideration OTC's prompt notification to the Dallas Field Division of its receipt of product that came into its possession inadvertently after the Order of Immediate Suspension had been served on it, a fact pointed out in Respondent's Exceptions to the Opinion and Recommended Ruling.

On the other hand, Larry Petit's experience as a cooperating source should have sensitized him to the threat of criminal activity posed by diversion of List I chemical products and the need for OTC's full compliance with both DEA regulations and the terms of its MOA. Further, while the financial audit was a positive business step, it did not focus on the more pressing need for regulatory compliance and strict record keeping actions necessary to ensure future accountability in the handling of listed chemical products.

The Acting Deputy Administrator concludes Respondent's registration with DEA would be inconsistent with the public interest. Although some positive efforts have been undertaken after initiation of these proceedings, OTC's track record has been one of non-compliance with recordkeeping requirements of List I chemical products and an inability to account for large quantities of List I chemical products. OTC further failed to fully comply with the terms of the MOA, failing to provide complete sales records, adequate inventory records or purchases records as required. Further, OTC's handling and delivery of List I chemical products at AIT's unregistered and insecure freight facility creates an unacceptable risk of diversion.

The Acting Deputy Administrator agrees with the Administrative Law Judge that DEA has insufficient assurances that Respondent, under the possible direction of Tim Petit, will be able to aggressively correct its List I chemical product handling practices and recordkeeping problems to a level that would justify its continued registration as being in the public interest. In the past, under the direction of Larry Petit, Respondent's disregard for the regulations and its obligations under the MOA make questionable its commitment and ability to comply with the DEA statutory and regulatory requirements designed to protect the public from the diversion of listed chemicals. *See, e.g., Seaside Pharmaceutical Co.,* 67 FR 12,580, 12,583 (2002); *Aseel, Incorporated, Wholesale Division,* 66 FR 35,459, 35,461 (2001).

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, 0044580RY, previously issued to OTC Distribution company, be, and it is, hereby revoked. The Acting Deputy Administrator further orders that any pending applications for renewal or modification of said registration be, and they hereby are, denied. This order is effective December 18, 2003.

Dated: November 26, 2003.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 03–31219 Filed 12–17–03; 8:45 am]

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DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 9, 2003.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor. To obtain documentation, contact Darrin King on 202–693–4129 (this is not a toll-free number) or E-Mail: *king-darrin@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Office of Disability Employment Policy (ODEP), Office of Management and Budget, Room 10235, Washington, DC 20503 (202–395–7316/this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Office of Disability Employment Policy.

Type of Review: New collection.

Title: National Survey of Sub-minimum Wage (14c) Certificate Recipients.

OMB Number: 1230–0NEW.

Affected Public: Not-for-profit institutions.

Type of Response: Reporting.

Frequency: One time.