requirements. Shan has demonstrated that it has brought the facility into compliance. The Consent Decree requires Shan to pay, based on its limited financial ability, a civil penalty of $101,000 in three annual installments, and provides that Shan will comply with reporting requirements set forth in the Consent Decree.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Shan Industries, LLC,* D.J. Ref. 90–5–2–1–08362/1. Such comments may also be sent by e-mail to *pubcomment-ees.enrd@usdoj.gov.*

The Consent Decree may be examined at the Office of the United States Attorney, District of New Jersey, 970 Broad Street, 7th Floor, Newark, NJ 07102, and at U.S. EPA Region 2, 290 Broadway, New York, NY 10007–1866. During the public comments period, the Consent Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.*

A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $6.50 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–3]

John J. Fotinopoulos; Revocation of Registration

On October 7, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Enforcement Administration, issued an Order to Show Cause to John J. Fotinopoulos (Respondent) of Gainesville, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, 002964JTY, as a distributor of listed chemicals, on the ground that his continued registration would be inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4) & 823(h). The Show Cause Order also proposed the denial of Respondent's pending applications for modification and renewal of his registration.

The Show Cause Order alleged that Respondent distributed listed chemicals to the non-traditional market. More specifically, the Show Cause Order alleged that in July 2003, Respondent moved his business from SW 47th St., Gainesville, Florida, to a trailer park located at SW Archer Road, Gainesville, Florida, but failed to request a modification of his registered location as required by DEA regulations until January 15, 2004. Show Cause Order at 2–3. The Show Cause Order further alleged that from July 2003 through January 2004, Respondent violated federal law by distributing listed chemicals from his new location which was not registered. *Id.* at 3.

The Show Cause Order also alleged that in 2001, a DEA investigator had inspected Respondent and found his recordkeeping and customer identification practices to be inadequate. *Id.* The Show Cause Order further alleged that during a May 2004 inspection, DEA investigators had again determined that Respondent's recordkeeping was inadequate, that he was unable to identify whether certain products were regulated because they contained listed chemicals, and that he was unfamiliar with the regulations pertaining to thresholds and regulated transactions. *Id.* Relatedly, the Show Cause Order alleged that Respondent told investigators that he kept information pertaining to his customers in his head. *Id.* Finally, the Show Cause Order alleged that Respondent's security arrangements were inadequate. *See id.*

Respondent, through his counsel, timely requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing in Gainesville, Florida, on April 19 and 20, 2005. At the hearing, both parties introduced documentary evidence and called witnesses to testify; both parties also submitted post-hearing briefs.

On October 11, 2006, the ALJ issued her decision.[1] In her decision, the ALJ found that four of the five statutory factors, *see* 21 U.S.C. 823(h), supported the revocation of Respondent's registration and the denial of his pending applications for renewal and modification of the registration. ALJ at 41. Neither party filed exceptions.

Having reviewed the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's findings of fact and conclusions of law except as expressly noted herein. I further adopt the ALJ's recommendation that Respondent's registration should be revoked and his pending applications for renewal and modification should be denied and make the following findings.

Findings of Fact

Respondent distributes assorted products including maps, cigarette lighters, rolling papers, prophylactics, batteries, and over-the-counter drug products to convenience stores, gas stations and liquor stores in northern Florida and southern Georgia. Gov. Ex. 27. Respondent is the holder of DEA Certificate Registration, No. 002964JTY, which authorizes him to distribute list I chemical products. ALJ at 3. Since 1998, Respondent has held a registration at his former residence which was located at 4000 SW 47th Street, Gainesville, Florida. *Id.* In early July 2003, Respondent moved from this address to a mobile home park located at 7117 SW Archer Road, Gainesville, Florida. Tr. 286.

On November 10, 2003, Respondent filed an application to renew his registration and paid the fee. Gov. Ex. 3; Tr. 289. On the application, Respondent sought to distribute pseudoephedrine and ephedrine from his new address. Gov. Ex. 3, at 2.

As explained in numerous DEA final orders, both pseudoephedrine and ephedrine currently have therapeutic uses. *See, e.g., Tri-County Bait Distributors,* 71 FR 52160, 52161 (2006).[2] Both chemicals are, however, regulated under the Controlled Substances Act because they are precursor chemicals which are easily extracted from non-prescription products and used in the illicit manufacture of methamphetamine, a Schedule II controlled substance. *See* 21 U.S.C. 802(34); 21 CFR 1308.12(d).

Methamphetamine is a powerful and highly addictive central nervous system

[1] The ALJ's Decision will be cited as ''ALJ.''

[2] The FDA is, however, currently proposing to remove combination ephedrine-guaifenesin products from its over-the-counter (OTC) drug monograph and to delare them not safe and effective for OTC use. *See* 70 FR 40232 (2005).

stimulant. *See, e.g., Tri-County Bait Distributors,* 71 FR at 52161. The illegal manufacture and abuse of methamphetamine pose a grave threat to this country. Methamphetamine abuse has destroyed numerous lives and families and ravaged communities. Moreover, because of the toxic nature of the chemicals which are used to make the drug, the illegal manufacture of methamphetamine causes serious environmental harms.[3] *Id.*

Because Respondent had changed his address, DEA did not renew his registration, which had an expiration date of December 31, 2003. ALJ at 10 (FOF 31). Respondent was told to contact the DEA Orlando office; on January 15, 2004, Respondent faxed a letter to that office informing it of his new address. *Id.*; Gov. Ex. 2.[4]

In January 2001, a DEA Diversion Investigator (DI) had conducted a cyclic investigation at Respondent's prior location. During this inspection, the DI instructed Respondent regarding the obligations of a registrant including the recordkeeping requirements and the duty to report suspicious orders. Tr. 207. The DI also provided Respondent with DEA Warning Notices; one of these documents specifically informed Respondent that pseudoephedrine and ephedrine drug products were being diverted into the illicit manufacture of methamphetamine. *Id.* at 207, 211–12; Gov. Ex. 6. Respondent acknowledged that during the inspection, the DI had discussed with him the subject of suspicious orders; in his testimony, he further asserted that the DI did not provide him with specific written guidelines pertaining to threshold amounts. Tr. 281–82.

During this inspection, the DI found Respondent's records to be ''in disarray.'' *Id.* at 208. The DI was ''unable to determine * * * who [Respondent's] customers were because they were not fully identified.'' *Id.* While Respondent provided a customer list to the DI, the list frequently stated just a store name and street. *Id.* at 210. Furthermore, because Respondent's records did not allow for the identification of specific customers, the DI was unable to determine whether Respondent had engaged in any regulated transactions. *Id.* at 208–09.

Respondent told the DI that he would maintain a ledger sheet for each of his listed chemical customers which would include the name of the person he dealt with. *Id.* at 209. The DI also suggested to Respondent that he keep the invoices for listed chemical products apart from his other invoices. *Id.* at 302. At the hearing, Respondent testified that he had ''attempted'' to do so, but had not ''succeeded'' in keeping the invoices ''separate.'' *Id.*

On direct examination, Respondent testified that he kept track of his sales of listed chemical products ''mostly * * * in my mind.'' *Id.* at 303. Respondent further stated that he ''visit[ed] the store[s] regular[ly],'' and that he knew ''something's wrong'' ''if [the store] ordered two weeks ago and * * * re-order[ed] after two weeks.'' *Id.* Respondent asserted, however, that he had ''never had any'' suspicious transactions. *Id.* at 304.

Under DEA's rules, a request to modify a registration is ''handled in the same manner as an application for registration,'' 21 CFR 1309.61, and in the case of a chemical distributor, requires an on-site inspection. Upon receipt of Respondent's January 2004 request to modify his registration, the same DI who had conducted the 2001 inspection told Respondent that he could not distribute listed chemicals from his new address because he was not registered there. Tr. 225.

In May 2004, the DI visited Respondent at his new address to conduct an on-site inspection. During this visit, the DI found that Respondent was in possession of both pseudoephedrine and ephedrine products. *Id.* at 226. More specifically, Respondent had ''several hundred boxes'' of listed chemical products. *Id.* at 219. Respondent was not aware that the products contained listed chemicals.[5] *Id.*

Moreover, during the visit, the DI asked Respondent to mark which of the products on his product list contained listed chemicals. *Id.* 218. While Respondent correctly indicated that products such as Mini Two-Way contained listed chemicals, he failed to mark any of the traditional products on his list such as Tylenol Cold and Tylenol Sinus, which contain pseudoephedrine. *Id.*

The DIs subsequently contacted Respondent's suppliers. One of the suppliers stated that it had sold ''almost 700,000'' dosage units of combination ephedrine products to Respondent after January 1, 2004, based on his representation to it ''[t]hat DEA had told him that he [could] keep purchasing that product.'' *Id.* at 227. The DI subsequently asked everyone in the Orlando diversion group whether they had given Respondent permission to continue handling listed chemical products; no one had. *Id.*

During the inspection, the DI asked Respondent about his recordkeeping, specifically, whether he was keeping a separate ledger as he had promised the investigator during the 2001 inspection. *Id.* at 215, 268. Respondent was not and told the DI that ''he didn't remember that conversation.'' *Id.* at 268.

The DI asked to see Respondent's purchase records from his suppliers. *Id.* at 228. Respondent could not provide them because they were not ''filed or organized in any manner.'' *Id.*

Respondent did provide the DI with seven ledger books containing copies of his sales invoices, which covered the period from September through December 2003. *Id.* at 239; *see also* Resp. Ex. 1 at 59–192. With respect to Respondent's listed chemical products, the invoices did not contain information regarding the product strength or number of tablets in a bottle/package. Tr. 240. While some of the invoices gave an address, others only listed the name of the store, the street it was on, and the city it was located in. *Id.* at 242–43; *see also* Gov. Ex. 29. For example, one of the invoices stated that products had been sold to a Chevron on ''Beach Boulevard, Jacksonville.'' Tr. 242–43. After conducting research using the internet and yellow pages, as well as driving the length of the street, the DI determined that there were three Chevron stations on the street. *Id.* at 243.

The ALJ also found that ''[m]ost of * * * Respondent's invoices failed to list the individual contact person for the customer.'' ALJ 13 (FOF 43, citing Tr. 243, Gov. Ex. 29, Resp. Ex. 1). Furthermore, one of the invoices indicated that Respondent had sold a case (144 bottles) of Max Brand, a product which typically contains sixty tablets of 60 mg. pseudoephedrine, *see* Gov. Ex. 25, at 4; Gov. Ex. 26, at 12, to

[3] The illicit manufacture of methamphetamine is an increasing problem in the State of Florida. *See Planet Trading, Inc.,* 72 FR 11055, 11056 (2007). As I noted in *Planet Trading,* during the period October 1, 2004, through September 30, 2005, law enforcement authorities seized 340 clandestine laboratories statewide. *Id.* By contrast, in 1999, only 20 clandestine laboratories were seized. *See* gov. Ex. 9.

[4] Respondent testified that at the time of his move, he phoned DEA headquarters to notify the Agency that he had changed his address. Tr. 286–87. Respondent further testified that he was told to contact the DEA Miami office, who told him to call the Orlando office. *Id.* According to Respondent's testimony, a person in the Orlando office told him to fax his new address to that office. *Id.* at 287. Respondent testified that he then faxed a written notice of his new address to DEA Orlando from the office of the trailer park where he now lives. *Id.* The ALJ did not specifically credit any of this testimony. *See* ALJ at 9 (FOFs 26 & 27). Nor do I. As the ALJ noted, Respondent acknowledged that he ''could not find a copy of that fax,'' *id.* at 9 (FOF 27; citing Tr. 287), and Respondent did not produce any phone records to support his assertions.

[5] Relatedly, at the hearing, Respondent was asked if he knew ''what the Code of Federal Regulations are [sic]?'' Tr. 319. Respondent answered: ''No.'' *Id.*

''Steve.'' Gov. Ex. 29, at 2. The invoice lacked essential identifying information such as the person's last name, a store name, and address. *See id.*[6]

At least one of the other invoices, which listed the sale of Max Brand products, contained no identifying information at all. Tr. 157 & 243, Resp. Ex. 1, at 402. When asked who had purchased the products listed on invoice number 361516, Respondent answered: ''I'm not sure. It's been quite some time. But I would say * * * it was to Steve again and probably a—or whatever.'' Tr. 308. Respondent further explained that he had not written the name down because he was either ''busy or tired.'' *Id.*

The DI testified that because of the condition of Respondent's records, he was unable to determine whether Respondent had engaged in any regulated transactions. *Id.* at 241. Moreover, when the DI asked Respondent what the threshold was for a regulated transaction, Respondent did not know. *Id.* at 242. When the DI discussed with Respondent the inadequacy of his recordkeeping, Respondent replied that ''he was just too busy'' to ''write all this information down.'' *Id.* at 243–44. Respondent further stated that the records ''were good enough for him.'' *Id.* at 244.

Respondent acknowledged that he could not tell if he had engaged in any regulated transactions ''without going back and going through every * * * invoice.'' *Id.* Regarding the identification of his customers, Respondent told the DI ''[t]hat he knew who they were and that all the information was kept in his head.'' *Id.* Furthermore, when asked by his counsel whether he had records that allowed him ''to identify more particularly where these various customers are?'' Respondent answered: ''Yes and no * * *. I [can] go home and find the exact address because some of the stores are listed in the phone book. Same thing the Gainesville phone book.'' *Id.* at 298.

During the on-site inspection, the DI also examined Respondent's security arrangements. Respondent was storing his listed chemical products in an aluminum storage shed that was mounted on a foundation of cement blocks. *Id.* at 250, 292. The storage shed was secured with a combination lock. *Id.* at 292. The shed apparently did not have an alarm. *Id.* Respondent further testified that he stored the products in the shed because his mobile home was too small, and ''nobody can see what is in the shed.'' *Id.* at 293. Respondent further stated that his customers did not come to his home and while people (neighbors) ''may see cases from different things * * * they wouldn't know what is the contents [of] the case.'' *Id.* at 294. According to the DI, Respondent's listed chemical products were commingled with other products in the shed. *Id.* at 252–53. Furthermore, Respondent would ''spend[] up to a week at a time on the road'' leaving his property unsupervised. *Id.* at 267.

The Government also called Jonathan Robbin, who testified as an expert witness. Mr. Robbin testified extensively regarding his findings regarding the market for listed chemical products, his review of the records of another distributor, and the expected monthly sales range to meet legitimate demand for listed chemical products at non-traditional retailers of these products such as gas stations, convenience stores, and liquor stores.

Unlike in numerous other cases, the Government did not produce a compilation of Respondent's sales of listed chemical products which showed the average sale amount per store, per month, over a sustained period of time. Instead, the Government asked Mr. Robbin to testify regarding several isolated invoices. While Mr. Robbin testified that some of Respondent's invoices were ''rather curious'' and were suggestive of excessive sales, *id.* at 154, he also stated that ''definitive conclusions'' could not be drawn from individual invoices. *Id.* at 156. Mr. Robbin further stated that ''[w]e should really analyze all their records to come up with definitive conclusions.'' *Id.*

I agree. A single invoice does not prove that a store engaged in excessive sales (and that its products were diverted) because it does not establish the length of time it took the store to sell the products. Without other invoices showing the dates and amounts of additional purchases, the possibility remains that the products remained in inventory for a substantial period and that the sales were to meet legitimate demand. In sum, the isolated invoices do no more than create a suspicion that Respondent engaged in excessive sales. Accordingly, I find that the Government's proof on the issue of excessive sales does not satisfy the substantial evidence test. *See NLRB* v. *Columbia Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939) (''Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established.'').[7]

Another issue in this case involved the employment status of Mr. Justin J. Paden, who serviced Respondent's customers in the Tallahassee area. Specifically, the Government attempted to prove that Mr. Paden was not an employee of Respondent because he did not withhold federal income tax from Mr. Paden's compensation, he did not pay the employer's share of Mr. Paden's Social Security taxes, and he did not pay worker's compensation or unemployment taxes. Tr. 310–11. The Government viewed Mr. Paden as an independent contractor, *id.* at 223 & 311, and considered Respondent's use of Mr. Paden to distribute listed chemical products to be a violation of the Controlled Substances Act. *Id.* at 224 (testimony of DI) (''any time that [Mr. Paden] sold product, it would actually be an illegal distribution'').

The ALJ found, however, that ''Mr. Paden worked under the direct supervision of the Respondent, and serviced only the Respondent's customers,'' that ''his pay was calculated'' based on his sales to Respondent's customers, and that he drove a van provided by, and insured by, Respondent. ALJ at 35. The ALJ thus concluded ''that the relationship between Mr. Paden and the Respondent was one of employer and employee, based on their conduct.'' *Id.* Ultimately, I conclude that it is immaterial whether Mr. Paden was an employee or an independent contractor because the evidence clearly establishes that Mr. Paden was subject to Respondent's control and therefore acted as his agent.

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical ''may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making this determination, Congress directed that I consider the following factors:

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

[6] While Respondent testified that ''Steve'' was ''Steve Lee, the owner of the Week 3, which is located on 576 South Edgewood, Jacksonville,'' Tr. 307, Respondent's customer list indicated that the name of the store located at this address was the ''Quick Trip Food Store.'' Gov. Ex. 28, at 3.

[7] This is not to say that the Government must review every single invoice and compile sales amounts for every single store. Rather, to establish excessive sales and support a finding of diversion, the Government need only analyze the sales made to selected stores. The Government cannot, however, rely solely on a single sale absent other evidence that the products were diverted.

(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.

Id. section 823(h).

''These factors are considered in the disjunctive.'' *Joy's Ideas*, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether a registration should be revoked or an application for a modification of a registration should be denied. *See, e.g.*, *David M. Starr*, 71 FR 39367, 39368 (2006); *Energy Outlet*, 64 FR 14269 (1999). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). In this case, I conclude that factors one, two, four, and five establish that Respondent's continued registration would be ''inconsistent with the public interest,'' 21 U.S.C. 823(h). Accordingly, Respondent's registration will be revoked and his pending applications for renewal and modification of the registration will be denied.

Factors One and Two—Maintenance of Effective Controls Against Diversion and Compliance With Applicable Laws and Regulations

The ALJ found that Respondent does not maintain effective controls against diversion. While the ALJ reasoned that the Government had not proved that Respondent's physical security arrangement were inadequate—because the storage shed appeared to be ''as secure as the DEA-approved past location in his mobile home,'' ALJ at 34—she further concluded that ''Respondent's failure to properly maintain records * * * is especially egregious.'' *Id.* at 35. While I agree with the ALJ's finding that Respondent's recordkeeping is inadequate, and her ultimate conclusion that this factor ''favors revocation,'' *id.* at 36, I further conclude that Respondent's proposed storage would provide inadequate security.

The applicable DEA regulation directs that eight factors be considered in assessing the adequacy of security. *See* 21 CFR 1309.71(b). Among the factors are ''[t]he type, form, and quantity of List I chemicals handled,'' ''[t]he location of the premises and the relationship such location bears on the security needs,'' ''[t]he type of building construction * * * and the general characteristics of the building,'' ''[t]he availability of electronic detection and alarm systems,'' and ''[t]he extent of unsupervised public access to the facility.'' *Id.* Here, the record establishes that Respondent proposed to store listed chemicals, which are easily converted into methamphetamine, in an aluminum storage shed (located apparently in his back yard), which was secured with a combination lock. Moreover, notwithstanding that Respondent was frequently away from his home for lengthy periods, the shed did not have an alarm.

It is obvious that such arrangements are inadequate to protect these products from theft. A thief using readily available bolt cutters would make short work of the lock, and without an alarm, a thief would be far more likely to succeed in stealing the chemicals.

The fact that similar arrangements were approved in the past does not estop the Agency from requiring greater security measures. Respondent did not rely on any representations of DEA personnel that the security arrangements at his new location met the Agency's requirements. Indeed, while DEA regulations provide that an ''applicant desiring to determine whether a proposed system of security controls * * * is adequate may submit materials and plans regarding the proposed security controls'' for review by either the Special Agent in Charge or the Office of Diversion Control, 21 CFR 1309.71(c), Respondent made no such submission. As found above, the illegal manufacture of methamphetamine has become an increasingly serious problem. Accordingly, whatever arrangements were previously deemed satisfactory are not necessarily still adequate to protect against theft. I therefore conclude that Respondent's proposed security arrangements would not provide effective controls against diversion.

The ALJ, however, also correctly observed that ''the inquiry into the effectiveness of the Respondent's controls 'does not end when products leave [their] physical location.' '' ALJ at 35 (quoting *D & S Sales*, 71 FR 37607, 37610 (2006)). As the ALJ recognized, maintaining proper records is also an essential part of providing effective controls against diversion. *See id.* Indeed, as the ALJ explained, Respondent's ''recordkeeping was so inadequate that neither he nor the DEA would be able to detect excessive purchases or other suspicious transaction behavior by his customers.'' *Id.* at 35–36.

As found above, many of Respondent's sale invoices lacked essential information. The invoices almost always failed to include information pertaining to product strength and count. The invoices also frequently lacked complete street addresses and the name of the contact person at a particular establishment; indeed, the testimony showed that on some streets there were multiple stores which used the same name. Moreover, in one instance, an invoice documented a large sale of a listed chemical product to a person identified only as ''Steve''; in another instance, purchaser information was completely missing.

While Respondent services approximately 150 stores, he testified that he kept track of his listed chemical sales to individual customers ''mostly * * * in my mind.'' Tr. 303. Moreover, Respondent further told the DI ''that all the information [regarding the identity of his customers] was kept in his head.'' *Id.* at 244. Respondent further contended that he could ascertain the exact address of his various customers ''because some of the stores are listed in the phone book.'' *Id.* at 298.

These statements are absurd. While it is true that the Government did not establish whether Respondent ever exceeded the 1,000 grams threshold and thus engaged in a regulated transaction, *see* 21 CFR 1300.02(b)(28)(i), as the ALJ found, ''this may well be attributed to * * * Respondent's deficient recordkeeping.'' ALJ at 36. Moreover, as the ALJ further explained, ''there was no means to determine if the Respondent's customers received in excess of the threshold amounts during any given month.'' *Id.* Relatedly, Respondent's purchase records were not ''filed or organized in any manner.'' Tr. 228.

While registrants who engage in regulated transactions are subject to additional recordkeeping and reporting requirements, *see* 21 CFR 1310.03, under DEA regulations, every registrant must maintain adequate records to monitor the receipt and distribution of listed chemical products. *See id.* 1309.71(b)(8) (directing the consideration of ''[t]he adequacy of [a] registrant's * * * systems for monitoring the receipt, distribution, and disposition of List I chemicals''). Absent maintaining proper records, legitimate registrants might fail to discover that their sales to an entity have exceeded the cumulative threshold and report the transaction. Furthermore, disreputable registrants could engage in regulated transactions and hide behind their poor recordkeeping to escape liability.

Finally, the record establishes that Respondent violated federal law by distributing listed chemical products from his new location without a valid registration. Under federal law, a registration is location specific. *See* 21 U.S.C. 822(f) (''A separate registration shall be required at each principal place of business * * * where the applicant * * * distributes * * * list I chemicals.''); *see also* 21 CFR 1309.23(a). Moreover, federal law clearly provides that a registrant is ''authorized to possess [or] distribute'' a listed chemical only ''to the extent authorized by their registration and in conformity with the other provisions of this subchapter.'' 21 U.S.C. 822(b). Furthermore, in contrast to a renewal application, which, if timely filed, keeps a registration in effect past its expiration date and until the Agency makes a final determination on the application, *see* 5 U.S.C. 558(c), a request for a modification is treated as a new application. *See* 21 CFR 1309.61 (a ''request for modification shall be handled in the same manner as an application for registration,'' and, if approved, ''the Administrator shall issue a new certificate of registration''). Accordingly, a request for modification does not authorize a registrant to engage in listed chemical activities until the modification is approved and the new certificate of registration is issued. *Cf. Orlando Wholesale, L.L.C.*, 71 FR 71555, 71557 (2006) (applicant's change of address following pre-registration inspection renders application moot).

The record contains numerous invoices showing that Respondent distributed listed chemicals out of his new and unregistered location. *See* Gov. Ex. 29; Resp. Ex. 1. Furthermore, the record contain substantial evidence establishing that even after Respondent was told by a DEA Investigator to stop distributing listed chemicals, he proceeded to obtain ''almost 700,000'' dosage units of combination ephedrine products from a distributor by representing to it that DEA had authorized him to continue to purchase them. *Id.* at 227. While the record does not contain invoices documenting the sale of these products, the quantity involved makes it obvious that Respondent was not purchasing the products for his personal use but rather to distribute them.[8] Respondent's distribution of list I chemicals after being told that he could no longer do so is egregious misconduct and manifests a flagrant disregard for the requirements of federal law. [9]

I thus concur with the ALJ's conclusion that this factor ''weighs heavily in favor of revocation.'' ALJ at 38. Indeed, were there no other evidence of Respondent's non-compliance with federal law and regulations, this conduct would provide reason alone to revoke his registration.[10]

Factor Four—Respondent's Experience in Distributing Listed Chemicals

According to the record, Respondent has been registered since 1998. Yet notwithstanding his several years of experience, Respondent has not learned very much about the products that are regulated and DEA's rules. Moreover, as explained above, Respondent's experience is characterized by his disregard for Federal laws and regulations and unsatisfactory business practices.

For example, when asked if he knew ''what the Code of Federal Regulations are [sic]?,'' Respondent answered: ''No.'' Tr. 319. Moreover, during the May 2004 pre-registration inspection, Respondent had ''several hundred boxes'' of pseudoephedrine products in his possession. *Id.* at 219, 226. Respondent was not aware, however, that the products contained this listed chemical. *Id.* at 219. Respondent was also unaware that products he carried such as Tylenol Cold and Tylenol Sinus contained pseudoephedrine. *Id.* at 218.

Beyond that, I note that Respondent's experience is characterized by (as charitably described by the ALJ) his ''lackadaisical attitude.'' ALJ at 39. As noted by the ALJ, Respondent justified his failure to adequately document his sales on the grounds that ''he was just too busy or too tired.'' *Id.* Respondent's attitude is simply incompatible with his continued participation in the distribution of list I chemicals. Accordingly, I adopt the ALJ's conclusion ''that this factor strongly favors revocation.''

Factor Five—Other Factors Relevant to Public Health and Safety

As found above, the illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation.[11] Cutting off the supply source of methamphetamine traffickers is of critical importance in protecting the public from the devastation wreaked by this drug.

While listed chemical products containing both ephedrine and pseudoephedrine have legitimate medical uses, DEA orders have established that convenience stores and gas-stations constitute the non-traditional retail market for legitimate consumers of products containing these chemicals. *See, e.g., Tri-County Bait Distributors*, 71 FR at 52161–62; *D & S* Sales, 71 FR at 37609; *Branex, Inc.*, 69 FR 8682, 8690–92 (2004). DEA has further found that there is a substantial risk of diversion of list I chemicals into the illicit manufacture of methamphetamine when these products are sold by non-traditional retailers. *See, e.g., Joy's Ideas*, 70 FR at 33199 (finding that the risk of diversion was ''real'' and ''substantial''); *Jay Enterprises, Inc.*, 70 FR 24620, 24621 (2005) (noting ''heightened risk of diversion'' if application to distribute to non-traditional retailers was granted).

Accordingly, ''[w]hile there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to [gas stations and convenience stores], DEA has nevertheless found that [these entities] constitute sources for the diversion of listed chemical products.'' *Joey Enterprises, Inc.*, 70 FR 76866, 76867 (2005). *See also TNT Distributors*, 70 FR 12729, 12730 (2005) (special agent testified that ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores'').[12] Here, it

[8] Respondent's purchases of products in this period also far exceeded the inventory found in his storage shed during the May 2004 inspection.

[9] The ALJ properly rejected the Government's contention that because Mr. Paden was not registered, Respondent violated federal law by distributing listed chemical products to him. Even if Mr. Paden was not an employee, but rather an independent contractor, the evidence shows that he was clearly Respondent's agent. *See* 21 U.S.C. 802(3) (defining ''agent'' as ''an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser'').

Under the plain language of the Act, an agent of a registered distributor is not ''required to register and may lawfully possess any * * * list I chemical * * * if such agent. * * * is acting in the usual course of his business.'' 21 U.S.C. § 822(c). *See also* 21 CFR 1309.24(a) (''The requirement of registration is waived for any agent * * * of a person who is registered * * * if such agent * * * is acting in the usual course of his * * * business[.]''); *Daniel Koller, D.V.M.,* 71 FR 66975, 66983 n.14 (2006).

[10] Relatedly, I acknowledge that there is no evidence that Respondent has been convicted of a crime, under either Federal or State laws, relating to controlled substances or listed chemicals.

[11] As found above, methamphetamine trafficking has increased substantially in Florida.

[12] *See OTC Distribution Co.*, 68 FR 70538, 70541 (2003) (noting ''over 20 different seizures of [gray market distributor's] pseudoephedrine product at clandestine sites,'' and that in eight-month period distributor's product ''was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone.''); *MDI Pharmaceuticals*, 68 FR 4233, 4236 (2003) (finding that ''pseudoephedrine products distributed by [gray market distributor] have been uncovered at numerous clandestine methamphetamine settings throughout the United States and/or discovered in

appears that all of Respondent's customers are convenience stores and gas stations, which are non-traditional retailers of list I chemical products and entities which DEA has repeatedly found are conduits for the diversion of these products into the illicit manufacture of methamphetamine.

Here, unlike in other cases where the Government's evidence established that a distributor had made excessive sales and that these sales supported a finding of diversion, the Government's proof does not support such a finding. Nonetheless, Respondent's wholly inadequate recordkeeping substantially hinders the efforts of this Agency and its local partners to investigate the suppliers of methamphetamine traffickers and the traffickers themselves. Moreover, even if Respondent's recordkeeping is attributable to neglect, it still impedes the protection of public safety. I therefore conclude that this factor also supports a finding that Respondent's continued registration would be inconsistent with the public interest.

In sum, Respondent violated Federal law by distributing products from an unregistered location. Indeed, this misconduct is especially egregious because he did so even after being told by a DEA official to stop. Respondent also does not maintain effective controls against diversion as evidenced by his wholly inadequate recordkeeping and the inadequate security he provided for list I products. Moreover, notwithstanding his years of experience distributing list I chemicals, Respondent clearly lacked knowledge of which products contained listed chemicals and he did not even know what the Code of Federal Regulations is. Finally, Respondent's attitude reflects indifference to his obligations under federal law and regulations. Given all of the above, it is indisputable that Respondent's continued registration would be inconsistent with the public interest.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, 002964JTY, issued to John J. Fotinopoulos be, and it hereby is, revoked. I further order that the pending applications for modification and renewal of the registration issued to John J. Fotinopoulos be, and they hereby are, denied. This order is effective June 4, 2007.

Dated: April 25, 2007.

Michele M. Leonhart,

Deputy Administrator.

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the possession of individuals apparently involved in the illicit manufacture of methamphetamine'').

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06–52]

Green Acres Farms, Inc.; Denial of Application

On February 6, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Green Acres Farms, Inc., (Respondent) of Tacoma, Washington. The Show Cause Order proposed to deny Respondent's pending application for registration as a bulk manufacturer of the Schedule I controlled substances marijuana and tetrahydrocannabinols, on the grounds that its registration would be inconsistent with the public interest, *see* 21 U.S.C. 823(a), and with the United States' obligations under the Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407. Show Cause Order at 1.

More specifically, the Show Cause Order alleged that on June 28, 2004, Respondent's owners, Mr. and Mrs. Keith Yale, submitted an application to DEA to manufacture marijuana and tetrahydrocannabinols and that DEA then sent the Yales a standardized questionnaire which all applicants for registration to manufacture controlled substances in Schedules I and II are required to complete. *See id.* The Show Cause Order alleged that Respondent's owners indicated on the questionnaire that the firm sought to grow marijuana to supply ''persons who qualify to receive marijuana under the Washington State Medical Use of Marijuana Act.'' *See id.* at 2. The Show Cause Order further alleged that Mrs. Yale stated on the questionnaire that she had obtained authorization from a physician to use marijuana and that she planned to use some of the marijuana grown by Respondent. *Id.* The Show Cause Order also alleged that Respondent intended ''to supply marijuana to patients in other states, which have laws that permit the 'medical use' of marijuana,'' and that Respondent also intended to distribute its marijuana to Washington-based pharmacies and cooperatives. *Id.* The Show Cause Order alleged that Respondent's owners had also stated that they intended to extract THC from their marijuana and develop an ingestible form of medication to create an alternative to smoked marijuana. *Id.*

The Show Cause Order further alleged that neither marijuana nor tetrahydrocannabinols have been approved under the Food, Drug and Cosmetic Act, as ''safe and effective'' for medical use, and neither drug has an ''accepted medical use in * * * the United States.'' *Id.* at 3 (citing 21 U.S.C. 321(p) & 812(b)(1)(B)). Relatedly, the Show Cause Order alleged that Respondent's proposed distribution of marijuana would constitute a felony under 21 U.S.C. 841(a)(1). *Id.* at 4. Finally, the Show Cause Order alleged that Respondent's proposed activity was not permitted under the Washington act. *See id.* at 4.

Respondent requested a hearing; the matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. Thereafter, the Government moved for summary disposition.[1]

The basis for the Government's motion was that marijuana and tetrahydrocannabinols have not been approved under the Food, Drug and Cosmetic Act, 21 U.S.C. 321(p), as ''safe and effective'' for medical use. Gov. Mot. at 3–4. The Government also argued that both marijuana and tetrahydrocannabinols are Schedule I controlled substances and ''have no currently accepted medical use in treatment in the United States.'' *Id.* (citing 21 U.S.C. 812(b)(1)(B)). Relatedly, the Government argued that ''there is a lack of accepted safety for use of these [drugs] under medical supervision.'' *Id.* (citing 21 U.S.C. 812(b)(1)(C)). The Government further noted this Agency's previous denial of a similar application to grow marijuana for medical use. *Id.* at 5 (citing *Church of the Living Tree,* 68 FR 17403 (2003)).

The Government also argued that in *United States* v. *Oakland Cannabis Buyer's Coop,* 532 U.S. 483 (2001), the Supreme Court had rejected the ''medical necessity'' defense raised by an entity which distributed marijuana for purportedly medical purposes. Gov. Mot. at 5. According to the Government, ''any distribution of marijuana as proposed by [Respondent] would constitute an unlawful distribution of a controlled substance in violation of 21 U.S.C. 841(a)(1), a felony.'' The Government further contended that unless and until ''these substances are

[1] Upon being directed by the ALJ to file a response to the Government's motion, Respondent sought a six month extension. The ALJ concluded, however, that an extension of such duration would unduly delay the proceedings. Instead, the ALJ granted Respondent a sixty day extension.