which is commonly diverted to the illicit manufacture of methamphetamine, a Schedule II controlled substance. Show Cause Order at 2. The Show Cause Order alleged that Mr. Abodabba had previously owned the Memphis Wholesale Company, which engaged in the distribution of List I chemicals under a DEA grandfather exemption. *See id.* The Show Cause Order further alleged that Mr. Abodabba had sold his interest in Memphis Wholesale to Mr. Mohammed Issa, who proceeded to distribute List I chemicals without obtaining a new DEA registration. *See id.* The Show Cause Order further alleged that Mr. Abodabba failed to notify DEA of the change in corporate ownership and that this resulted in Memphis Wholesale ''conducting continuing distribution activities without authorization.'' *Id.*

The Show Cause Order further alleged that while Mr. Abodabba told DEA Diversion Investigators that he only intended to sell ''traditional'' pseudoephedrine products, several of his proposed suppliers sold only ''non-traditional pseudoephedrine and ephedrine products.'' *Id.* at 2–3. The Show Cause Order also alleged that several of Mr. Abodabba's proposed customers had been found to be selling excessive amounts of ephedrine products and that other proposed customers had been receiving List I chemical products from distributors who had either surrendered a registration or were the subject of a show cause proceeding. *See id.* at 3. Finally, the Show Cause Order alleged that ''[i]t appears that Mr. Abodabba is attempting to 'churn' his distribution activities in order to evade scrutiny, and if registered, would likely supply retailers who already have an excessive source of supply.'' *Id.* at 4. The Show Cause Order also notified Respondent of its right to a hearing.

The Show Cause Order was served on Respondent by certified mail, return receipt requested at its proposed registered location; on July 26, 2005, DEA received the signed return receipt card. Since that time, neither Respondent, nor anyone purporting to represent it, has responded. Because (1) more than thirty days have passed since Respondent's receipt of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived its right to a hearing. *See* 21 CFR 1309.53(c). I therefore enter this final order without a hearing.

Findings

I take official notice of the records of the Tennessee Secretary of State. According to those records, on June 25, 2004, the Tennessee Secretary of State filed a notice of determination that grounds existed for dissolving Respondent. Thereafter, on September 17, 2004, the Secretary filed a certificate of dissolution thereby administratively dissolving Respondent. Under Tennessee law, ''[a] corporation administratively dissolved continues its corporate existence but may not carry on any business except that necessary to wind up and liquidate its business and affairs * * * and notify claimants.'' Tenn. Code Ann. § 48–24–202 (West. 2006) (citations omitted). Respondent is thus prohibited from engaging in business operations involving the distribution of products.

Under DEA regulations, a registration terminates ''if and when'' a registrant ''discontinues business.'' 21 CFR 1309.62(a). While there is no provision addressing the status of a pending application when the applicant discontinues business, it would make no sense to grant an application to register an entity which cannot engage in business. Therefore, because Respondent is no longer authorized to engage in business other than for the purpose of winding up its affairs, it is not entitled to registration and it is unnecessary to consider whether Respondent's registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(h).

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) and 0.104, I hereby order that the previously submitted application of Nashville Wholesale Company, Inc., for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is denied. This order is effective October 2, 2006.

Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14523 Filed 8–31–06; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–4]

Tri-County Bait Distributors; Denial of Application

Introduction and Procedural History

On August 11, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Tri-County Bait Distributors (Respondent) of Dorchester, South Carolina. The Show Cause Order proposed to deny Respondent's application for a DEA Certificate of Registration as a distributor of the List I chemicals ephedrine and pseudoephedrine on the ground that its registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(h).

The Show Cause Order specifically alleged that Respondent was seeking to distribute products containing ephedrine and pseudoephedrine, which are precursor chemicals that are used in the production of methamphetamine, a schedule II controlled substance. Show Cause Order at 1. The Show Cause Order alleged that Respondent was proposing to sell these products exclusively to convenience stores and combination bait shops/convenience stores, and that these establishments are part of the non-traditional or gray market for these products. *Id.* at 4. The Show Cause Order further alleged that Respondent's owner, Mr. Terry L. Carroll, had stated that ''he had no prior experience in the sale or marketing of OTC medications,'' and that the distribution of List I chemicals would be ''approximately 20 percent of his business.'' *Id.* at 2. The Show Cause Order also alleged that ''many smaller or non-traditional stores * * * purchase inordinate amounts of these products and become conduits for the diversion of listed chemical[s] into illicit drug manufacturing.'' *Id.* at 2–3. Finally, the Show Cause Order alleged that Respondent's proposed ''product mix and sales of combination ephedrine products are inconsistent with the known legitimate market and known end-user demand for products of this type'' and that the registration of Respondent ''would likely lead to increased diversion of List I chemicals.'' *Id.* at 4.

Respondent requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing in Charleston, South Carolina, on October 5, 2004. Both the Government and Respondent submitted post-hearing briefs.

On July 6, 2005, the ALJ issued her decision. The ALJ concluded that the Government had proved by a preponderance of the evidence that Respondent's registration would be inconsistent with the public interest. *See* ALJ at 15–17. The ALJ thus recommended that Respondent's application be denied. *Id.* at 17. Neither party filed exceptions.

Having considered the record as a whole, I hereby issue this decision and final order. Except as expressly noted herein, I adopt the ALJ's findings of fact and conclusions of law. For the reasons set forth below, I concur with the ALJ's conclusion that granting Respondent's application for registration would be inconsistent with the public interest and therefore deny Respondent's application.

Findings of Fact

Respondent is a supplier of bait, fishing gear, and other items including over-the-counter medicines that do not contain List I chemicals to tackle shops, convenience stores, gas stations and marinas that are located in several rural counties in South Carolina. Respondent is located in Dorchester, South Carolina, and is owned by Mr. Terry Carroll. Because Respondent's business is seasonal in nature with a large variation in sales between summer and winter months, on November 21, 2002, Mr. Carroll applied for a registration to distribute the List I chemicals ephedrine and pseudoephedrine.

Methamphetamine and the Market for List I Chemicals

Both ephedrine and pseudoephedrine have therapeutic uses. They are, however, regulated under the Controlled Substances Act because they are precursor chemicals that are easily extracted from legal over-the-counter products and used in the illicit manufacture of methamphetamine. *See* 21 U.S.C. 802(34). Methamphetamine is a powerful and addictive central nervous system stimulant, *see A–1 Distribution Wholesale*, 70 FR 28573 (2005), and is a schedule II controlled substance. 21 CFR 1308.12(d).

The illegal manufacture and abuse of methamphetamine pose a grave threat to this country. Methamphetamine abuse had destroyed numerous lives and families and ravaged communities. The manufacture of methamphetamine also causes serious environmental harms because of the toxic nature of the chemicals. Tr. at 96.

The State of South Carolina, which is where Respondent does business, has experienced a substantial increase in the number of illegal methamphetamine labs. According to the testimony of a DEA special agent who serves as the agency's Clandestine Laboratory Coordinator for South Carolina, in 2001 DEA found ten clandestine lab sites in the State. Tr. 100. In 2002, DEA found 100 clandestine labs, and in 2003, the agency found 130 sites. *Id.* The DEA Special Agent further testified that in 2004, DEA expected that it would find between 165 to 185 labs. *Id.* These labs are predominately found in rural areas of the State. *Id.* at 95.

The DEA Special Agent further testified that while the amount of methamphetamine that can be produced from ephedrine and pseudoephedrine varies with the skill of a methamphetamine cook, it is possible to obtain a yield of 100 percent. The Special Agent also testified that even with a 50 percent yield, 1000 grams of ephedrine or pseudoephedrine would yield 500 grams of methamphetamine which has a street value of $50,000. *Id.* at 100.

Another Government witness, Mark Rubbins, who was then Chief of the Domestic Chemical Control Unit in the Chemical Control Section at DEA Headquarters, testified by written declaration. Mr. Rubbins testified that the traditional market for products containing ephedrine and pseudoephedrine was comprised of chain grocery stores, national pharmacy chains, and large retail outlets. These stores ''normally sell pseudoephedrine in lower strengths such as 30 mg. tablets'' and in smaller unit sizes such as blister packs not exceeding 48 dosage units per package. Gov. Exh. 6. at 5. Moreover, manufacturers of products sold in this market either sell direct to the chain stores or through large nationally recognized distributors. *Id.* at 6.

Mr. Rubbins further testified that beginning in the mid-1990s, following the enactment of the Domestic Chemical Diversion Control Act of 1993 and the Comprehensive Methamphetamine Control Act of 1996, traditional manufacturers stopped selling larger strength products such as those containing a single active ingredient of 60 mg. of pseudoephedrine in bottle sizes. Traditional market retailers also stopped selling large count sizes of products containing List I chemicals. *See id.* at 7–9.

Mr. Rubbins further testified that while traditional manufacturers were reducing the size and strength of their List I products, smaller manufacturers and distributors continued to market high strength products in high dosage counts such as 60 mg. single entity pseudoephedrine sold in bottles containing 60, 96 or 100 tablets. *See id.* at 7 & 9. Mr. Rubbins testified that these products ''pass through several layers of distribution'' and are now sold in such non-traditional establishments as small convenience stores, gas stations, liquor stores, and head shops. *Id.* at 6. According to Mr. Rubbins, non-traditional retailers ''tend to knowingly sell in large quantities to 'smurfers,' '' who purchase the product on behalf of methamphetamine manufacturers. *Id.* at 7. Mr. Rubbins also testified that based on data obtained in lab seizures, he had concluded that DEA's enforcement efforts involving pseudoephedrine products may have caused methamphetamine traffickers to return to using combination ephedrine products. *See id.* at 10.

The Government also submitted the declaration of Mr. Jonathan Robbin, the President and founder of Ricercar, Inc. Mr. Robbin's firm ''specializes in the statistical analysis of demographic, economic, geographic and survey data for the purpose of locating, sizing and segmenting markets for a wide variety of consumer goods sold at retail.'' Gov. Exh. 9, at 1. Mr. Robbin has credibly testified as an expert witness on the market for ephedrine and pseudoephedrine products in numerous proceedings including Federal criminal prosecutions, *see, e.g., United States* v. *Sdoulam*, 398 F.3d 981, 989–91 (8th Cir. 2005), and DEA proceedings. *See, e.g. D & S Sales*, 71 FR 37607 (2006).

In this proceeding, Mr. Robbin testified that based on his study of U.S. Economic Census Data, data collected by the National Association of Convenience Stores (NACS), and commercially available point of sale transaction data, he had found that convenience stores sell only a very small percentage of the market for non-prescription drugs. *See* Gov. Exh. 9, at 5–7. According to Mr. Robbin's analysis, 97 percent of all sales of non-prescription drugs occur in drug stores, supermarkets, large discount merchandisers, and electronic shopping/mail-order houses. *Id.* at 5. Mr. Robbin further testified that Economic Census Data indicate that sales of non-prescription drugs in convenience stores both selling and not selling gasoline account for only 2.2% of total sales of all convenience stores that handle these products.[1] *Id.* at 5–6.

Mr. Robbin testified that the normal expected retail sales of pseudoephedrine products in convenience stores ''may range between $0 and $40 per month, with an average

[1] The ALJ found that Mr. Robbin ''stated that his analysis showed that over-the-counter drugs containing pseudoephedrine accounted for only 2.6 percent of all sales of health and beauty products in convenience stores and only 0.05 percent of such stores' total non-gasoline sales.'' ALJ at 9. The ALJ did not, however, cite the specific portion of the Robbin declaration that she based her finding on. My review of the Robbin declaration concludes that the figures do not refer to the percentage of pseudoephedrine sales, but rather the sale of all nonprescription drugs in convenience stores based on data compiled by the National Association of Convenience Stores. *See* Gov. Exh. 9, at 6.

of $21.60.'' *Id.* at 9. With respect to ephedrine products, Mr. Robbin further testified that the expected sales range of these products in a convenience store is ''between $0 and $25 per month, with an average of $12.58.'' *Id.* Mr. Robbin further testified that ''[a] sale of over $100 a month (5 times expectation) would be expected to occur in random sampling about once in a million raised to the tenth power.'' [2] *Id.* Based on NACS surveys indicating that the average gross margin on these products is about 40%, Mr. Robbin concluded that ''a convenience store may be expected to spend an average of about $12 per month acquiring an inventory of pseudoephedrine tablets at wholesale from a distributor or $7.50 per month stocking ephedrine tablets.'' *Id.*

Finally, Mr. Robbin rendered an opinion based on information in the DEA Diversion Investigator's (DI) report that Mr. Carroll had ''hope[d] to sell $100.00 worth of List I chemicals to each [retail] customer every month.'' *Id.* at 14. Mr. Robbin opined that this would ''translate into retail sales of $167 per month, over eight times normal expectation'' and that ''[s]uch an amount would be extraordinarily far beyond what could normally be expected to be sold to ordinary consumers by such stores.'' *Id.* at 15. He further concluded that ''all of these listed retailers are not participating in the traditional market for these products and could not sell $167 or more of them per month in ordinary commerce for their intended purpose as non-prescription drugs.'' *Id.* at 16.

The Pre-Registration Investigation

In February 2003, a DEA Diversion Investigator (DI) visited Respondent at its proposed register location to conduct a pre-registration investigation. The DI met with Mr. Carroll and interviewed him regarding Respondent's proposed business in List I chemicals. Mr. Carroll told the DI that he needed to distribute List I chemicals because his customers were asking for them and because the products had a high profit margin. *See* ALJ at 10. Mr. Carroll further told the DI that he expected to sell approximately $100 per month of List I chemicals per customer and that he expected List I chemicals to comprise twenty percent of his revenue and possibly more if he was able to increase his customer base. *See id.* With respect to the twenty percent figure, Mr. Carroll testified, however, that he had not done a market analysis and that the figure was just ''wishful thinking'' and had no basis. Tr. 158. With respect to the $100 per month per customer figure, ALJ found that Mr. Carroll testified that the amount included all of the medicine he sold and not just that containing List I chemicals. *See* ALJ Dec. at 12; *see also* Tr. at 182–83.

The DI further testified that during the interview, Mr. Carroll informed him that he intended to sell both Mini Thins and Max Alert. The DI testified that both products contain 25 mg. of ephedrine and 200 mg. of guaifenesin and that he had never seen these products in a traditional retailer. Tr. 16. The DI further testified that these products have been found at clandestine lab sites ''on many occasions.'' *Id.* at 57. Mr. Carroll also told the DI that he wanted to sell several nationally branded products such as Advil Cold & Sinus and Tylenol Sinus. *See* ALJ at 12. Mr. Carroll testified, however, that ''he had no objection to DEA placing restrictions on his ability to sell certain products.''*Id.*

Mr. Carroll also testified that he had no connection to any illegal methamphetamine cooks. Tr. at 167. He also testified that to his knowledge, none of his customers were involved in the illegal production or distribution of methamphetamine. *Id.* at 167–68.

During the investigation, Mr. Carroll gave the DI the name of his expected supplier. Following the on-site inspection, the DI contacted the supplier. The supplier told the DI that it had a minimum order requirement of 36 60-count bottles. This prompted the DI's concern because 60-count bottles are commonly found at clandestine lab sites. Mr. Carroll also gave the DI a list of his potential List I chemical customers. The DI contacted thirteen of them. Two of the customers stated that they did not intend to sell List I chemical products. Several of the other customers stated that while they would buy List I products from Respondent, they also had other suppliers. This also raised a concern because it indicated that a lot of product would be coming into these stores and suggested the possibility of diversion. On cross-examination, however, the DI testified that at least one of the customers stated that he would buy from whoever offered the best price. Tr. at 74. The record is unclear, however, as to whether the other stores that already had a List I chemical supplier told the DI that they would limit their purchases to the supplier that offered the best price.

The DI also testified that Respondent proposed to store the List I chemicals in a room of an old mobile home. According to the DI, the room had ''a wooden door of not very heavy construction,'' with a single cylinder doorknob lock and no deadbolt. *Id.* at 21. Moreover, the room had ''regular glass-plate windows'' and did not have an alarm system. *Id.* at 22. Mr. Carroll testified, however, that he had replaced the mobile home's exterior door and that this door had a lock on it. *Id.* at 162. Mr. Carroll's testimony does not indicate what type of lock it is. *See id.* Mr. Carroll further testified that he was building a barn with an office and a refrigerated room in which he would store medicine. *Id.* at 161.

The ALJ further found that the DI ''conceded that Respondent's facility minimally met DEA guidelines.'' ALJ Decision at 11. While the DI testified that the security ''was minimum, very minimum,'' he added that ''it was very questionable.'' Tr. at 20. I therefore do not accept the DI's testimony as conclusive proof that Respondent's facility met our guidelines.

The DI further testified that Mr. Carroll indicated that he had no experience in the sale of List I chemicals. *Id.* at 19. Mr. Carroll's wife testified, however, that she sold these products in her bait shop at the retail level and that Mr. Carroll had run the store when she was tending to her daughter. *Id.* at 129–130. Mrs. Carroll further testified that she had observed Mr. Carroll handling these products while working in her bait shop, and that she had never observed anything improper in the way he had handled them. *Id.* at 130. She further testified that her husband was an honest, hardworking man, and ''would never do anything that would compromise the welfare of our family.'' *Id.*

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless I determine that the registration would be ''inconsistent with the public interest.'' 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;

(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.

[2] While it is not entirely clear whether Mr. Robbin was discussing a sale of pseudoephedrine or ephedrine, his reference that the $100 amount was ''5 times expectation'' suggests that the statement pertains to pseudoephedrine. I thus find that the statement refers to pseudoephedrine sales.

Id. ''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 an application for registration should be denied. *See, e.g., David M. Starr*, 71 FR 39367 (2006); *Energy Outlet*, 64 FR 14269 (1999). In this case, I conclude that factors one, four and five require the denial of Respondent's application.

Factor One—Maintenance of Effective Controls Against Diversion

The ALJ acknowledged that Respondent's proposed location for storing List I products is inadequate. As the record demonstrates, the proposed location was a room in an old mobile home that contained two plate-glass windows, and had an entry door of insubstantial construction that was secured by only a single cylinder lock. *See* 21 CFR 1309.71(b)(3) (requiring consideration of ''[t]he type of building construction comprising the facility and the general characteristics of the building''). Moreover, while Respondent testified that he had replaced the exterior door to the building, his testimony did not indicate what type of lock was installed in the door. Furthermore, the mobile home does not have an alarm system. *See id.* at 1309.71(b)(4). The proposed location clearly does not provide adequate security to protect List I chemicals from diversion through theft. *See*, *e.g.*, *David M. Starr*, 71 FR 39367, 39368 (2006).

The ALJ nonetheless concluded that because Mr. Carroll testified that he was building a new facility, the record does not establish whether or not Respondent would provide adequate security. *See* ALJ at 15. I disagree—the Government did prove that Respondent's proposed registered location would not provide adequate security. The speculative possibility that Respondent would eventually construct a facility that meets DEA's standards does not refute the Government's evidence.

Beyond that, the evaluation of an application requires significant agency resources including the employee travel time and inspection time necessary to conduct an on-site, pre-registration investigation. Moreover, applicants for any DEA registration should familiarize themselves with the regulations and other policies such as those contained in the Chemical Handlers Manual before applying.

In this case, approximately six months elapsed from the date of the pre-registration investigation until the issuance of the Show Cause Order. Yet at no time during this period did Respondent notify DEA that he was planning on building a new facility. It was only after service of the Show Cause Order—and apparently at the hearing—that Respondent stated his intention to build a new facility.

Because there must be some finality in this process, I decline to allow applicants to challenge a show cause order's allegation that their proposed location lacks proper security by asserting at a hearing that they plan improvements. Once a show cause order is issued, an applicant can challenge an allegation that the security of the proposed location is inadequate only by showing that the facility met DEA guidelines at the time of the on-site inspection, or that it had corrected any security deficiencies so as to be in compliance and had submitted adequate proof of its compliance to DEA prior to issuance of the order.[3]

I thus conclude that Respondent does not have effective controls against diversion. This factor alone supports a finding that Respondent's registration would be inconsistent with the public interest.

Factors Two—Compliance With Applicable Laws

The ALJ concluded that there was ''no evidence or indication that Respondent has not complied with applicable Federal, State, and local laws.'' ALJ at 16. I agree and conclude that this factor weighs in favor of a finding that Respondent's registration would not be inconsistent with the public interest.

Factor Three—The Applicant's Prior Record of Relevant Criminal Convictions

The ALJ further found that there was no evidence that Mr. Carroll has a prior criminal conviction for a drug-related offense. Mr. Carroll, however, admitted on the application that he had previously been convicted of a crime relating to controlled substances or chemicals. *See* Gov. Exh. 1, at 1. On the application, Mr. Carroll explained that he ''had a possession charge in 1980,'' but that he had not ''had a problem since.'' *Id.* at 2. The Government offered no evidence to the contrary. In light of the age of the conviction, I conclude that it is not probative in assessing whether Respondent's registration would be inconsistent with the public interest. I thus conclude that this factor does not bar registration.

[3] In the event that a proposed location's lack of security was the only reason that the application was denied, an applicant can always reapply after the necessary improvements have been completed.

Factor Four—Past Experience of the Applicant in the Distribution of Chemicals

The ALJ found that Mr. Carroll had no prior experience distributing List I chemicals. I agree.

I further acknowledge the testimony that Mr. Carroll had sold List I products while working in his wife's store. I do not consider this to be relevant experience. The regulatory requirements applicable to List I chemical distributors are numerous and complex. *See* 21 CFR Pts. 1309 & 1310. Moreover, retail distributors of ephedrine and pseudoephedrine were generally exempt from the recordkeeping and reporting requirements.[4] Furthermore, Mr. Carroll does not claim that his experience working as a retail clerk required him to perform any of the recordkeeping and reporting requirements applicable to a non-retail distributor.

DEA has recognized that an applicant's lack of experience in distributing List I chemicals creates a greater risk of diversion and thus weighs heavily against the granting of an application. *See Starr*, 71 FR at 39368; *Jay Enterprises*, 70 FR 24620, 24621 (2005); *ANM Wholesale*, 69 FR 11652, 11653 (2004). Respondent's lack of relevant experience thus weighs against granting the application.

Factor Five—Other Factors That Are Relevant To and Consistent With Public Health and Safety

Respondent argues that the sale of List I chemical products is legal activity and that these products are sold ''not only in drug stores and supermarkets, but in the very same mom and pop stores to which [it] intends to sell them.'' Resp. Proposed Findings at 3. Respondent further argues that the Government has not shown any link between itself and illicit manufacturers of methamphetamine. *See id.*

I acknowledge Respondent's contention that the sale of List I chemical products is a legal activity and that Congress has not prohibited non-traditional retailers from selling these products. Numerous DEA cases recognize, however, that the sale by non-traditional retailers of List I chemical products containing ephedrine and pseudoephedrine is an area of particular concern in preventing

[4] This discussion reflects the regulatory landscape pre-dating the Combat Methamphetamine Epidemic Act of 2005. Under provisions of the Combat Meth. Act that become effective on September 30, 2006, retail distributors are required to maintain a logbook which records the name and address of each purchaser of pseudoephedrine or ephedrine products, the date and time of the sale, the product name and the quantity.

diversion of these products into the illicit manufacture of methamphetamine. *See Joey Enterprises*, 70 FR 76866, 76867 (2005). As *Joey Enterprises* explains, ''[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.'' *Id. 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''); *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 an 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 the possession of individuals apparently involved in the illicit manufacture of methamphetamine'').

Moreover, clandestine lab seizures have frequently found high-strength, high count List I chemical products, thus indicating that these are the preferred products for illicit methamphetamine manufacturers. *See OTC Distribution*, 68 FR at 70541, *Shani Distributors*, 68 FR 62324, 62325 (2003); *MDI Pharmaceuticals*, 68 FR at 4236. Respondent proposed to sell similar high strength, high count products. *See Xtreme Enterprises*, 67 FR 76197, 76195 (2002); Tr. at 57 (special agent testified that Mini Thins and Max Alert bottles have been found at clandestine lab sites ''on many occasions'').

Moreover, all of Respondent's proposed customers participate in the non-traditional market for ephedrine and pseudoephedrine products.[5]

DEA final orders recognize 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, substantial and compelling''); *Jay Enterprises*, 70 FR at 24621 (noting ''heightened risk of diversion'' should application be granted); *Xtreme Enterprises*, 67 FR at 76197. Under DEA precedents, an applicant's proposal to sell into the non-traditional market weighs heavily against the granting of a registration under factor five. So too here.[6]

I also reject Respondent's contention that it entitled to a registration because ''[t]he government has established no link between [it] and the small illicit laboratories that manufacture methamphetamine.'' Resp. Proposed Findings at 3. Under the public interest standard of section 823(h), the Government is not required to prove that an applicant (or one of the stores the applicant intends to sell to) is linked to illicit meth. manufacturers in order to sustain a denial of an application or revoke a registration. Rather, the statute directs that I consider a variety of factors; an applicant's lack of a direct link to illegal drug distribution is just one of several factors to be considered in determining the public interest. *See* 21 U.S.C. 823(h).

Because of the methamphetamine epidemic's devastating effects, DEA has repeatedly denied an application when an applicant proposed to sell into the non-traditional market and analysis of one of the other statutory factors supports the conclusion that granting the application would create an unacceptable risk of diversion. Thus, in *Xtreme Enterprises*, my predecessor denied an application observing that respondent's ''lack of criminal record, compliance with the law and willingness to upgrade her security system are far outweighed by her lack of experience with selling List I chemicals and the fact that she intends to sell ephedrine almost exclusively in the gray market.'' 67 FR at 76197. More recently, I denied an application observing that the respondent's ''lack of a criminal record and any intent to comply with the law and regulations are far outweighed by his lack of experience and the company's intent to sell ephedrine and pseudoephedrine exclusively to the gray market.'' *Jay Enterprises*, 70 FR at 24621. *Accord Starr*, 71 FR at 39368–69; *Prachi Enterprises*, 69 FR 69407, 69409 (2004).

I further note that each of these cases was decided before the recent enactment of the Combat Methamphetamine Epidemic Act of 2005. *See* USA Patriot Improvement and Reauthorization Act of 2005, Pub. L. 109–177, Tit. VII, 120 Stat.192, 256–275 (2006). I acknowledge that in the course of considering the Act, Congress rejected proposals to schedule pseudoephedrine products as a controlled substance, and thus prohibit their sale by non-traditional retailers. *See*, *e.g.* H.R. 314, 109th Cong. § 104 (2005). Congress did not, however, overturn DEA precedents interpreting the public interest standard of 21 U.S.C. 823(h) as authorizing the denial of an application to distribute List I chemicals on grounds similar to those established by the record in this case. *Cf. Commodity Futures Trading Comm'n* v. *Schor*, 478 U.S. 833, 846 (1986) (When Congress revisits a statute, its ''failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.'') (internal quotations and other citation omitted).

Here, the factors that support denial of the application outweigh those that support granting it. Respondent's proposed security measures are plainly inadequate and are thus grounds alone to deny the application. Moreover, Respondent's owner lacks relevant experience in the distribution of List I chemicals and proposes to sell to non-traditional retailers, a market in which the risk of diversion is substantial. I thus conclude that granting Respondent's application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) and 0.104, I hereby order that the previously submitted application of Tri-County Bait Distributors for a DEA Certificate of Registration as a distributor of List I

[5] I acknowledge Respondent's contention that List I chemical products are sold in ''the very same mom and pop stores to which [it] intends to sell them.'' Resp. Proposed Findings at 3. However, the purpose of this proceeding is to determine whether granting Respondent's application to be a distributor would be consistent with the public interest. In short, that other firms have established their qualifications to distribute List I chemical products to non-traditional retailers is not relevant in assessing Respondent's application.

[6] I do not rely on the Government's expert testimony that Respondent's expected sales could not occur in ordinary commerce. The expert testimony was not based on actual sales figures. *See*, *e.g.*, *D & S Sales*, 71 FR at 37611. Rather, it was an estimate, and there is no evidence establishing that Mr. Carroll discussed with his customers how much product they would purchase from Respondent. Moreover, the ALJ did not resolve the factual dispute as to whether the estimate included only sales of List I chemicals, or of all the OTC medicines Respondent intended to sell. Because our precedents do not require an evaluation of an applicant's estimated sales level to justify denial of an application, I need not resolve this factual question. In accordance with D & S Sales, the use of expert testimony showing that a registrant's actual sales greatly exceeded legitimate demand remains a valid means of proving diversion.

chemicals be, and it hereby is, denied. This order is effective October 2, 2006.

Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sato Pharmaceutical, Inc.; Denial of Application

On August 5, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Sato Pharmaceutical, Inc., (Respondent) of Torrance, California. The Show Cause Order proposed to deny Respondent's pending application for registration as a non-retail distributor of List I chemicals on the ground that Respondent's registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(h); Show Cause Order at 1.

The Show Cause Order specifically alleged that Respondent sells dietary supplements and Asian healthcare products to convenience stores and small markets. *See* Show Cause Order at 2. The Show Cause Order alleged that Respondent had been illegally importing from Taiwan and Japan pseudoephedrine 60 mg. products that were sold under the ''Stona'' brand. *See id.* The Show Cause Order further alleged that Respondent had been engaged in this activity for over ten years. *See id.* Finally, the Show Cause order alleged that Respondent had sold these products to distributors who also lacked a DEA registration. *See id.* The Show Cause Order further advised Respondent of its right to a hearing. *Id.*

The Show Cause Order was served by certified mail. Respondent, through its counsel, initially requested a hearing; the matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. Several days later, however, Respondent withdrew its request for a hearing and the ALJ terminated the proceeding. Thereafter, the investigative file was forwarded to me for final agency action. Because Respondent has expressly waived its right to a hearing, I hereby enter this final order based on relevant material in the investigative file and make the following findings.

Findings

Pseudoephedrine is a List I chemical that has a lawful therapeutic use. It is, however, easily extracted from over-the-counter 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). As noted in numerous prior DEA orders, ''methamphetamine is an extremely potent central nervous system stimulant.'' *David M. Starr,* 71 FR 39637 (2006). Methamphetamine abuse has destroyed lives and families, ravaged communities, and created serious environmental harms.

Respondent is a United States subsidiary of a Japanese pharmaceutical company. Respondent, which is located in Torrance, California, sells a variety of products including over-the-counter medicines and dietary supplements. Among these products were ''Stona'' brand pseudoephedrine pills and liquid cold remedies that were made in Japan and Taiwan.

In March 2004, DEA was advised by a regulatory consultant to Respondent's U.S. subsidiary that the company had been importing and distributing several Stona brand pseudoephedrine products without the registrations required under the Controlled Substances Act. *See* 21 U.S.C. 823(h); *id.* 957(a) & 958(c)(2). At a meeting, the consultant further told several DEA Diversion Investigators (DIs) that Respondent had been importing and distributing products containing pseudoephedrine and phenylpropanolamine (PPA) for at least 10 years but that Respondent had stopped importing PPA products. According to the consultant, Respondent was never registered to either import or distribute List I chemicals because neither he (the consultant) nor the company knew that registration was required.

The investigation also determined that Respondent had sold pseudoephedrine products to other distributors who were not registered. Moreover, the investigative file states that Respondent failed to file form DEA–486, Import/Export Declaration, for its importations of the pseudoephedrine. *See* 21 CFR 1313.12(a).

Respondent also advised DEA that it had a sizeable inventory of pseudoephedrine products at its Torrance, California facility.[1] Respondent informed DEA that it had ''quarantined'' the inventory; it also requested authorization to export the products back to its facilities in Japan and Taiwan.

On August 9, 2004, DEA approved a one time distribution by Respondent to Leiner Health Products, a DEA registered exporter, for the purpose of returning the products. On or about August 27, 2004, the shipment occurred.

Thereafter, on September 29, 2004, Respondent applied for a DEA registration to distribute pseudoephedrine. On February 23, 2005, DEA conducted a pre-registration investigation at Respondent's Torrance facility. Respondent's officials told the DIs that it was seeking registration to distribute the remaining portion of the product that it had previously returned to Taiwan and which it had not been able to sell. In particular, Respondent sought authorization to import a one-time shipment of 7,000 bottles containing 24 tablets of 30 mg. pseudoephedrine from its Taiwan facility. Respondent's officials further told the DIs that it was no longer manufacturing pseudoephedrine products.

The DIs determined that Respondent had in place adequate procedures for identifying and verifying customers, recordkeeping and reporting, and for the handling and delivery of the products. The DIs also determined that Respondent would provide adequate security for the products.

The DIs also conducted verifications of Respondent's customers. Respondent's customers are a combination of small groceries, pharmacies, and medical providers that primarily serve Asian-American communities. Eighty percent of Respondent's customers are located in Southern California. The DIs also ran criminal background checks on Respondent's officers and found no derogatory information. The DIs further determined that with the exception of the conduct described above, Respondent was in compliance with applicable laws and had obtained a California permit for chemical precursors.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless the registration would be ''inconsistent with the public interest.'' 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;

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

[1] The inventory included approximately 6992 bottles (120 ml.) of Stona cough syrup, 3915 packages of 24 Stona tablets, 2943 packages of 24 Stona caplets, and 720 packages of 24 Stona S caplets.