

investigative file), I conclude that Respondent was not in compliance with federal immigration laws and that Respondent does not possess the required state and/or local business licenses. Moreover, the information sought with respect to Respondent's managing members was essential to evaluate whether the firm would maintain "effective controls against diversion." *Id.* § 823(h)(1). Based on the information contained in the investigative file that one of Respondent's managing members had previously operated a business which distributed List I chemicals without a valid registration and Respondent's failure to provide any documentation showing that this individual no longer has a management or ownership interest in it, I conclude that Respondent does not maintain effective control against diversion.

Respondent's change of address provides further reason to deny its application. Under the Controlled Substances Act, a registration is location specific. See 21 U.S.C. 822(e) ("A separate registration shall be required at each principal place of business * * * where the applicant * * * distributes * * * list I chemicals."). Respondent applied for a registration at 9500 Satellite Blvd., # 230, Orlando, Fl. It was at this location that the pre-registration investigation was conducted and the adequacy of Respondent's security controls was evaluated. See 21 CFR 1309.71(b). Respondent's change of its location after DEA conducted the pre-registration inspection renders moot the information obtained regarding its security measures and its application for registration at its prior place of business. Furthermore, Respondent has not submitted an application for its new location. Because Respondent applied to distribute List I chemicals from the Satellite Blvd. location and it is no longer in business at that location, I conclude that granting its application for a registration would be inconsistent with the public interest.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) & 0.104, I hereby order that the application of Respondent Orlando Wholesale L.L.C., for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is, denied. This order is effective January 10, 2007.

Dated: December 1, 2006.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Taby Enterprises of Osceola, Inc.; Denial of Application

On November 23, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Taby Enterprises of Osceola, Inc., of Plant City, Florida (Respondent). The Show Cause Order proposed to deny Respondent's pending 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. See 21 U.S.C. 823(h) & 824(a).

The Show Cause Order specifically alleged that Respondent was proposing to distribute List I chemical products to convenience stores, which are non-traditional retailers of these products. See Show Cause Order at 2. The Show Cause Order further alleged that Respondent had no experience in the distribution of List I chemical products. See *id.* The Show Cause Order also alleged that Respondent provided a customer list which he represented as including his "established customers." *Id.* The Show Cause Order alleged, however, that when DEA investigators contacted these establishments, several "were out of business" and only a small number of them "expressed any interest in acquiring listed chemical products from" Respondent. *Id.* The Show Cause Order thus alleged that Respondent had "not provided complete and accurate information to DEA," and that DEA therefore could not determine whether Respondent would comply with federal law and protect against the diversion of listed chemical products. *Id.*

The Show Cause Order was served by certified mail, return receipt requested. On December 3, 2005, Respondent acknowledged receipt of the Show Cause Order as evidenced by 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 based on relevant material found in the investigative file and make the following findings.

Findings

Ephedrine and pseudoephedrine are List I chemicals that, while having therapeutic uses, are easily extracted from lawful 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 DEA orders, "methamphetamine is an extremely potent central nervous system stimulant." Sujak Distributors, 71 FR 50102, 50103 (2006); A-1 Distribution Wholesale, 70 FR 28573 (2005). Methamphetamine abuse has destroyed lives and families and ravaged communities. Moreover, because of the toxic nature of the chemicals used to make the drug, its manufacture creates serious environmental harms. David M. Starr, 71 FR 39367 (2006).

Respondent is a Florida corporation which is located at 1912 Jim Redman Parkway, Plant City, Fl., 33566. Respondent has been in business since December 2002; its President and Owner is Mr. Muhammad Aslam Butt.

On May 2, 2005, Respondent applied for a registration as a distributor of the List I chemicals pseudoephedrine and ephedrine. Thereafter, on June 17, 2005, two DEA Diversion Investigators (DIs) went to Respondent's proposed registered location to conduct a pre-registration investigation. The DIs inspected Respondent's facility and interviewed Respondent's owner.

The DIs determined that Respondent sells sundry items including tobacco products, lighters, various over-the-counter drugs, batteries and small toys, etc., to local convenience stores and gas stations. Respondent also operates a retail store at the same location.

During the interview, Respondent informed the DIs that he wanted to expand his product line to include cold medicines that contain pseudoephedrine such as Advil, Nyquil/Dayquil, Tylenol Sinus, Tylenol Cold, Contact and Tylenol Flu. Respondent also told the DIs that he intended to sell Mini-Thins Two Way and other ephedrine products. Mr. Butt further stated that he would be the only individual who would handle List I chemical products and that he would purchase the products from F & S Distributing, Inc., and Price Master Corp.

According to the investigative file, Mr. Butt has no prior experience in the wholesale distribution of List I chemicals. Moreover, Mr. Butt told the DIs that he does not verify the identity of his customers by asking them to present an ID.

The DIs also explained to Mr. Butt DEA's recordkeeping requirements. The DIs then sought and obtained a list of the firm's established customers; the DIs subsequently attempted to visit eleven of them. Only two of these establishments expressed any interest in buying List I products from Respondent. As for the other nine stores visited by the DIs, two of the stores could not be found at the address given by Mr. Butt. At another two stores, the owner/manager could not recall whether he had ever purchased merchandise from Respondent. At a third location, the owner stated that he had never purchased any merchandise from Respondent. At three other stores, the owners told the DIs that they had only purchased a limited amount of items from Respondent and would not consider buying any List I products from it as they already had other suppliers. Finally, at another store, the owner had never heard of Respondent.

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;
- (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.

"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., *Starr*, 71 FR at 39367; *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, Four, and Five, establish that granting Respondent's application would be inconsistent with the public interest and that its application should be denied.

Factor One—Maintenance of Effective Controls Against Diversion

The investigative file establishes that Respondent does not have in place effective controls against diversion. According to the file, Respondent does not verify the identity of his customers. Verifying the identity of purchasers of List I chemicals is essential to ensuring that these products are being bought to meet legitimate consumer demand and not for use in the illicit manufacture of methamphetamine. See 21 CFR 1309.71(b)(8) (requiring the assessment of "[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"). Respondent's practice of failing to identify its customers thus raises a substantial risk that if it was granted a registration, its products would be diverted. *Cf. Alra Laboratories, Inc. v. DEA*, 54 F.3d 450, 451 (7th Cir. 1995) ("[a]n agency rationally may conclude that past performance is the best predictor of future performance"). I thus conclude that Respondent, if granted a registration, would not maintain effective controls against diversion.

In support of this finding, I further note the discrepancies between the customer information Respondent provided and what the DIs found during the customer verifications. This is not a case where there are slight variances, but rather material differences between the information provided by an applicant and that discovered by DEA investigators. While Respondent represented that the list included his established customers, four of the stores did not appear to have had a business relationship with Respondent, and even among those that did have a relationship, most of them had no interest in purchasing List I chemical products from it. Finally, some of the stores could not be found at the address provided by Respondent. This information does not inspire confidence that the products Respondent would handle would remain within the legitimate chain of distribution. I thus conclude that this factor establishes that Respondent's application should be denied.

Factors Two and Three—Compliance With Applicable Law and the Applicant's Prior Record of Relevant Criminal Convictions

The file does not contain any evidence that Respondent has failed to comply with applicable Federal, State or local laws. The file also does not contain any evidence that Respondent,

or its owner, has been convicted of any drug related criminal offense.

Factor Four—The Applicant's Past Experience in the Manufacture or Distribution of Chemicals

According to the investigative file, neither Respondent, nor its owner, has any experience in the wholesale distribution of List I chemical products. Numerous DEA final orders have made clear that because of the potential for diversion, an applicant's (and its controlling person's) lack of experience in distributing List I chemicals is a factor which weighs heavily against granting an application for a registration. *Tri-County Bait Distributors*, 71 FR 52160, 52613 (2006); *Jay Enterprises*, 70 FR 24620, 24621 (2005); *ANM Wholesale*, 69 FR 11652, 11653 (2004).

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

Numerous DEA orders recognize that convenience stores and gas-stations constitute the non-traditional retail market for legitimate consumers of products containing pseudoephedrine and ephedrine. See, e.g., *Tri-County Bait Distributors*, 71 FR at 52161; *D & S Sales*, 71 FR 37607, 37609 (2006); *Branex, Inc.*, 69 FR 8682, 8690–92 (2004). DEA orders also establish that the sale of certain List I chemical products by non-traditional retailers is an area of particular concern in preventing diversion of these products into the illicit manufacture of methamphetamine. See, e.g., *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 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, during clandestine lab seizures, DEA has frequently found 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, MDI Pharmaceuticals, 68 FR at 4236. While Respondent proposed to sell traditional products, he also sought to sell similar high count products.

Significantly, all of Respondent’s proposed customers participate in the non-traditional market for ephedrine and pseudoephedrine products. DEA 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). 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.

Because of the methamphetamine epidemic’s devastating impact on communities and families throughout the country, 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, 67 FR 76195, 76197 (2002), my predecessor denied an application observing that the 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.” 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 Prachi Enterprises, 69 FR 69407, 69409 (2004).

Here, Respondent clearly lacks effective controls against diversion, has no experience in the wholesale distribution of List I chemical products, and yet intends to distribute these products to non-traditional retailers, a market in which the risk of diversion is substantial. Given these findings, it is indisputable that granting Respondent’s application would be “inconsistent with the public interest.” 21 U.S.C. 823(h).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) & 0.104, I hereby order that the application of Respondent Taby Enterprises of Osceola, Inc., for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is, denied. This order is effective January 10, 2007.

Dated: December 1, 2006.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA #290E]

Controlled Substances: Established Initial Aggregate Production Quotas for 2007

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2007.

SUMMARY: This notice establishes initial 2007 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: *Effective Date:* December 11, 2006.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA Title 21 United States Code section 826 (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 Code of Federal Regulations (CFR)

0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The 2007 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2007 to provide adequate supplies of each substance for: The estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. 826(a) and 21 CFR 1303.11). These quotas do not include imports of controlled substances for use in industrial processes.

On August 29, 2006, a notice of the proposed initial 2007 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (71 FR 51214). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before September 19, 2006.

Five responses were received within the published comment period resulting in comments on a total of 25 schedule I and II controlled substances. The responses commented that the proposed aggregate production quotas for alfentanil, aminorex, cocaine, codeine (for conversion), dihydrocodeine, ecgonine, fentanyl, hydrocodone, hydromorphone, levorphanol, methadone, methadone intermediate, methamphetamine, methylphenidate, morphine (for conversion), nabilone, noroxymorphone (for conversion), oxycodone, oxycodone (for conversion), oxymorphone, oxymorphone (for conversion), remifentanyl, sufentanyl, tetrahydrocannabinols and thebaine were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

DEA has taken into consideration the above comments along with the relevant 2006 manufacturing quotas, current 2006 sales and inventories, 2007 export requirements, additional applications received, and research and product development requirements. Based on this information, the DEA has adjusted the initial aggregate production quotas for alfentanil, aminorex, amobarbital, codeine (for conversion), dextropropoxyphene, dihydrocodeine, gamma hydroxybutyric acid, ibogaine, hydrocodone, metazocine, nabilone, noroxymorphone (for conversion), oxycodone, oxycodone (for conversion), oxymorphone, oxymorphone (for conversion), remifentanyl, sufentanyl,