

pursuant to subsection (f) of section 823, these factors are considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See, e.g., Energy Outlet, 64 FR 14,269 (1999). See also, Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

The Deputy Administrator finds factors one, four and five relevant to the pending application for registration.

As to factor one, maintenance of effective controls against diversion of listed chemicals into other than legitimate channels, the Deputy Administrator has previously held that this factor and 21 CFR 1309.71(b)(8) encompass more than mere physical security of listed chemicals while in storage or transit. See e.g., Al-Alousi, Inc., 70 FR 3,561 (2005) [inability of applicant to adequately verify location and identities of prospective customers considered under factor one]; OTC Distribution Company, 68 FR 70,538, 70,542 (2003); see also Aqui Enterprises, supra 67 FR 12,276; Alfred Khalily, Inc., 64 FR 31,289 (1999).

Titan's proposed process of purchasing in-transit shipments of listed chemicals and redirecting them to other buyers fails to provide adequate protection and safeguards for preventing listed chemicals from diversion into other than legitimate channels. The company's methods would not require it to ever have physical control of the chemicals, nor would it ensure compilation of adequate inventories or complete and accurate records. It also fails to provide for the consistent and accurate verification of identities of the persons and entities which would ultimately be receiving the listed chemicals.

In sum, Titan's proposed methods run counter to the distribution and accountability safeguards envisioned under the Controlled Substances Act and its implementing regulations and fail to provide effective controls against diversion of listed chemicals. Accordingly, factor one weighs against granting the pending application.

With regard to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant based on the applicant's lack of knowledge and experience regarding the laws and regulations governing handling of list I chemical products. In prior DEA decisions, this lack of experience in handling list I chemical has been a factor in denying pending

applications for registration. See, e.g., Direct Wholesale, supra, 69 FR 11,654; ANM Wholesale, 69 FR 11,652 (2004); Extreme Enterprises, Inc., 67 FR 76,195 (2002).

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor also weighs against granting the application.

Unlawful methamphetamine use is a growing public health and safety concern throughout the United States and Southeast. Ephedrine and pseudoephedrine are precursor products needed to manufacture methamphetamine and operators of illicit methamphetamine laboratories regularly acquire the precursor products needed to manufacture the drug from convenience stores and gas stations which, in prior DEA decision, have been identified as constituting the grey market for list I chemical products. While there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found these establishments serve as sources for the diversion of large amounts of listed chemical products. See, e.g., ANM Wholesale, supra, 69 FR 11,652; Xtreme Enterprises, Inc., supra, 67 FR 76,195; Sinbad Distributing, 67 FR 10,232 (2002); K.V.M. Enterprises, 67 FR 70,968 (2002).

The Deputy Administrator has previously found that many considerations weighed heavily against registering a distributor of list I chemicals because, "[v]irtually all of the Respondent's customers, consisting of gas station and convenience stores, are considered part of the grey market, in which large amounts of listed chemicals are diverted to the illicit manufacture of amphetamine and methamphetamine." Xtreme Enterprises, Inc., supra, 67 FR at 76,197.

Because of its proposed methods, Titan could not identify the specific ephedrine and pseudoephedrine products it intended to distribute or their quantities and strengths. It also could not identify any specific customers or suppliers. While Titan did not state whether or not it would enter the grey market, it is reasonable to infer its business practices would invite eventual participation in that sector. The company intends to search nationwide for bulk quantities of chemicals becoming available for sale while in-shipment. It would buy them at a discount and redirect them to new purchasers, ideally without ever exercising physical possession of the product. Titan would thus be engaging

in apparently random transactions, occurring whenever it discovers an opportunity to buy low and resell at a profit.

Mr. Pelt did tell investigators that if Titan's application was granted, he would try to develop business relationships with large chain drug stores. However, given his company's lack of specific prospective buyers and suppliers, its inability to identify products, quantities and strengths and its aggressive business practices, coupled with the absence of effective controls described under factor one above, the Deputy Administrator views the risk of Titan entering the gray market as real and significant, once it discovers buyers from that sector willing to purchase listed chemicals at prices yielding Titan large profits.

The Deputy Administrator is also concerned with Mr. Pelt's refusal to consider alternative business methods and his inaccurate representations regarding the purportedly similar business practices of two other registrants. This suggests that Mr. Pelt and Titan would either be unwilling or unable to successfully fulfill the significant responsibilities of a registrant.

Based on the foregoing, the Deputy Administrator concludes that granting the pending application would be inconsistent with the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders the pending application for DEA Certificate of Registration, previously submitted by Titan Enterprises, Inc., be, and it is hereby is, denied. This order is effective April 14, 2005.

Dated: February 14, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03-24]

TNT Distributors, Inc., Denial of Application

On March 31, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to TNT Distributors, Inc., (Respondent/TNT) proposing to deny its

application for a DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged in substance that granting Respondent's application to distribute list I chemicals to what DEA has identified as the "gray market," would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h) and 824(a).

Respondent, through counsel, requested a hearing on the issues raised by the Order to Show Cause and the matter was docketed before Administrative Law Judge Mary Ellen Bittner. Following prehearing procedures, a hearing was held in Nashville, Tennessee on April 20, 2004. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Subsequently, both parties filed Proposed Findings of Fact, Conclusions of Law, and Argument.

On December 3, 2004, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Opinion and Recommended Ruling), recommending that Respondent's application for a Certificate of Registration as a distributor of listed chemical products be denied. Neither party filed exceptions to the Opinion and Recommended Ruling and on January 11, 2005, Judge Bittner transmitted the record of these proceedings to the Deputy Administrator.

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

On September 11, 2002, Respondent, a Tennessee corporation solely owned by Ms. Mary Blackard, submitted an application for DEA Certificate of Registration as a distributor of list I chemicals, seeking authority to distribute pseudoephedrine, ephedrine and phenylpropanolamine. Later, Respondent withdrew its request to distribute phenylpropanolamine.

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals which are legitimately manufactured and

distributed in single entity and combination forms as decongestants and bronchodilators, respectively. Both are used as precursor chemicals in the illicit manufacture of methamphetamine and amphetamine. As testified to by government witnesses at the hearing and as addressed in previous DEA final orders, methamphetamine is an extremely potent central nervous system stimulant and its abuse is a persistent and growing problem in the United States. See e.g., Direct Wholesale, 69 FR 11,654 (2004); Branex, Inc., 69 FR 8,682 (2004); Yemen Wholesale Tobacco and Candy Supply, Inc., 67 FR 9,997 (2002); Denver Wholesale, 67 FR 99,986 (2002).

A Special Agent from DEA's Chattanooga, Tennessee Resident Office testified regarding the rapid proliferation of clandestine methamphetamine laboratories in Tennessee and its adjoining states and described prevalent methods of local production. He estimated that 80 to 90 percent of ephedrine and pseudoephedrine being used locally to manufacture methamphetamine was being obtained from convenience stores and described the multiple health hazards and social costs stemming from the production and abuse of methamphetamine. He characterized the local methamphetamine addiction problem as "epidemic."

In the Special Agent's opinion, the bulk of pseudoephedrine and ephedrine products distributed through local convenience stores were being obtained for illicit purposes. While listed chemicals were also available from local chain drug and discount stores, in his opinion, when manufacturers obtained precursor products from those establishments, it was usually done by shoplifting.

Ms. Blackard has worked in a North Carolina veterinary practice for 14 years, where she was responsible for ordering, recordkeeping, disposal and inventorying controlled substances commonly used by veterinarians. She then moved to Tennessee and filed incorporation papers for TNT, which began selling merchandise to independent convenience stores. As of the date of the DEA hearing, TNT had 66 customers, about 20 of which were in the metropolitan Nashville area. It primarily sold and distributed tobacco products, some over-the-counter medications, toys, air fresheners and novelty items.

Ms. Blackard testified she decided to apply for a DEA registration because her customers wanted listed chemicals and she believed her company could not compete successfully without offering that product line. At the hearing she

initially testified that list I chemicals would account for about 15 to 20 percent of TNT's total sales. On cross-examination she later conceded that "was just a number I threw out here."

In November/December 2002, DEA investigators conducted a preregistration investigation of Respondent's proposed registered location, her residence, which was located in a rural area. The agent conducting the investigation testified Ms. Blackard did not know at the time that list I chemical products could be used to manufacture methamphetamine and she thought Mini-Thins, an ephedrine 25 mg, combination product which she desired to distribute, were used for "dietary reasons." She told the agent that she had no experience with listed chemicals but did have experience maintaining controlled substance records. Ms. Blackard provided investigators a list of about 20 proposed customers, most of which were area convenience stores.

The agent who conducted the preregistration investigation testified Ms. Blackard appeared reasonable and receptive to the information he provided regarding the dangers of diversion and responsibilities of a registrant. He also acknowledged that her proposed storage arrangement complied with DEA regulations.

At the hearing, Ms. Blackard testified she was willing to comply with DEA requirements and that her recordkeeping practices would be more stringent than required by regulations. She testified TNT would maintain a small customer base of around 100 stores, that she would closely monitor sales and stop selling to any suspicious customers. She would also take action to enhance the security of products stored at her residence. While she originally listed Mini Thins among her intended products, at the hearing Ms. Blackard indicated that if registration was approved, she would not carry that item and limit TNT's line to such name brands as Advil Cold and Sinus and Nyquil.

A Supervisory Diversion Investigator from DEA's Nashville office testified that diversion was a major problem in Tennessee and DEA had ordered immediate suspensions of several wholesalers who were selling gray market products to area convenience stores and gas stations. He observed that once a distributor becomes registered to handle list I chemicals, it can order whatever chemicals are included in its registration, including gray market products. In the supervisory investigator's opinion, once registered, Respondent would likely seek to

increase its customer base and, considering the methamphetamine problem in Tennessee, "we don't need any more people handling these products."

By declaration, the Government introduced evidence regarding pseudoephedrine sale and the convenience store market from Mr. Jonathan Robbin, a consultant in marketing information systems and databases, who is an expert in statistical analysis and quantitative marketing research.

Using the 1997 United States Economic Census of Retail Trade, Mr. Robbin tabulated data indicating that over 97% of all sales of non-prescription drug products, including non-prescription cough, cold and nasal congestion remedies, occur in drug stores and pharmacies, supermarkets, large discount merchandisers, mail-order houses and through electronic shopping. He characterized these five retail industries as the traditional marketplace where such goods are purchased by ordinary customers.

Analyzing national sales data specific to over-the-counter, non-prescription drugs contain pseudoephedrine, Mr. Robbin's research and analysis showed that a very small percentage of the sales of such goods occur in convenience stores—only about 2.6% of the HABC [Health and Beauty Care] category of merchandise or 0.05% of total in-store (non-gasoline) sales. He determined that the normal expected retail sales of pseudoephedrine tablets in a convenience store would range between \$10.00 and \$30.00 per month, with an average monthly sales figure of about \$20.00 and that sales of more than \$100.00 in a month would be expected to occur in a random sampling about once in one million to the tenth power, a number he characterized as nearly equivalent to the number of atoms in the universe. He further stated that the current convenience store gross margin in the health and beauty care category is about 40 percent, so that such a store would be expected to spend an average of \$12.00 per month acquiring its inventory of pseudoephedrine products from a distributor.

Pursuant to 21 U.S.C. 823(h), the Deputy Administrator may deny an application for a Certificate of Registration if she determines that granting the registration would be inconsistent with the public interest as determined under that section. Section 823(h) requires the following factors be considered in determining the public interest:

(1) Maintenance of effective controls against diversion of listed chemicals into other than legitimated channels;

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

(3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

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

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

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, these factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or combination of factors, and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See, e.g., *Direct Whole*, 69 FR 11,654; *Energy Outlet*, 64 FR 14,269 (1999); *Henry J. Schwartz, Jr., M.D.*, 54 FR 16,422 (1989).

As to factor one, maintenance by the applicant of effective controls against diversion, the Deputy Administrator agrees with Judge Bittner that TNT's proposed physical security arrangements were adequate and that Ms. Blackard had the ability and willingness to maintain accurate records of the handling of listed chemicals. Judge Bittner also found Ms. Blackard to be a credible witness and believed her explanation that she sought registration because other distributors holding registrations had a competitive advantage over her company and that Ms. Blackard knew her customers and would not handle products DEA told her to avoid.

However, Judge Bittner acknowledged existence of a previously published DEA final order denying registration to an applicant much like Respondent. Judge Bittner concluded that she was restrained by that precedent, *Xtreme Enterprises, Inc.*, 67 FR 76,195 (2002). See also *Shop It for Profit*, 69 FR 1,311 (2003); *William E. "Bill" Smith d/b/a B & B Wholesale*, 69 FR 22,559 (2004); *Shani Distributors*, 68 FR 62,324 (2003) and *Branex Incorporated*, 69 FR 8,682 (2004). Specifically, Judge Bittner found *Xtreme Enterprises* "virtually indistinguishable" from the instant case.

In *Xtreme Enterprises*, the Deputy Administrator found many considerations weighed heavily against registering a distributor of list I chemicals because, "[v]irtually all of the Respondent's customers, consisting of gas station and convenience stores, are

considered part of the gray market, in which large amounts of listed chemicals are diverted to the illicit manufacture of amphetamine and methamphetamine." *Xtreme Enterprises, Inc.*, *supra*, 67 FR at 76,197. Based on that case, Judge Bittner concluded that factors one (maintenance of controls against diversion) and five (other factors relevant to and consistent with public health and safety), weighed against granting Respondent's application.

Judge Bittner also concluded Respondent had complied with applicable Federal, State and local law and had never been convicted of a crime relating to controlled substances or listed chemicals, thus finding that factors two and three weighed in favor of registration. With regard to factor four, the applicant's past experience in distributing listed chemicals, Judge Bittner found Ms. Blackard had no previous experience distributing list I chemicals. However, her prior experience in handling and maintaining records of controlled substances rendered that factor essentially neutral. The Deputy Administrator agrees with these conclusions.

Judge Bittner summarized that, "in light of the decision in *Xtreme Enterprises, Inc.*, *supra*, which I regard as controlling, I conclude that I have no choice but to recommend against granting Respondent's application." However, she went on to state that if the Deputy Administrator were to decide *Xtreme Enterprises* was not controlling, she would recommend that Respondent's application be granted, with restrictions as to the quantities of ephedrine and pseudoephedrine it could purchase and sell. The Deputy Administrator declines this invitation to deviate from sound agency precedent.

Unlawful methamphetamine production and use is a growing public health and safety concern throughout the United States and specifically in the State of Tennessee. Pseudoephedrine and ephedrine are the precursor products used to manufacture methamphetamine and operators of illicit laboratories in Tennessee predominantly acquire their precursor chemicals from Respondent's intended customer base. While Ms. Blackard demonstrated sincerity and intent to avoid contributing to this scourge, the risks of diversion once listed chemicals leave her control and enter the gray market are real, substantial and compelling.

The Deputy Administrator therefore concludes Judge Bittner correctly applied DEA precedent. As in *Xtreme Enterprises, Inc.*, Ms. Blackard's lack of a criminal record, her previous

compliance with the law and expressed willingness to comply with regulations and attempt to guard against diversion are far outweighed by her intent to sell ephedrine and pseudoephedrine almost exclusively, in the gray market.

This reasoning has been consistently applied by the Deputy Administrator in a series of recently published final orders denying registration to potential gray market distributors. See, *Volusia Wholesale*, 69 FR 69,409 (2004); *CWK Enterprises, Inc.*, 69 FR 69,400 (2004); *J & S Distributors*, 69 FR 62,089 (2004); *Express Wholesale*, *supra*, 69 FR 62,086; *Absolute Distributing, Inc.*, 69 FR 62,078 (2004); *Value Wholesale*, 69 FR 58,548 (2004); *John E. McRae d/b/a J & H Wholesale*, 69 FR 51,480 (2004).

Based on the foregoing, the Deputy Administrator concludes that granting Respondent's pending application would be inconsistent with the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for a DEA Certificate of Registration, previously submitted by TNT Distributors, Inc., be, and it hereby is, denied. This order is effective April 14, 2005.

Dated: February 14, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Tysa Management, d/b/a Osmani Lucky Wholesale; Denial of Application

On July 23, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mr. Ty Osmani, President, Tysa Management, d.b.a. Osmani Lucky Wholesale (hereinafter referred to as "OLW") proposing to deny its application executed on October 15, 2003, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of OLW would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h).

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to OLW at its proposed registered location in Denison, Texas

and was received on August 2, 2004. According to the investigative file, DEA received a letter from Tysa Osmani (Mr. Osmani) dated August 20, 2004, waiving the applicant's right to a hearing and requesting that the firm be issued a registration to distribute ephedrine.

Accordingly, the Deputy Administrator finds that OLW has waived its hearing right. See, *Aqui Enterprises*, 67 Fed. Reg. 12567 (2002). After considering relevant material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53(b) and (d). The Deputy Administrator finds as follows:

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). As noted in previous DEA final orders, Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance.

Methamphetamine is an extremely potent central nervous system stimulant and its illicit manufacture and abuse are ongoing public health concerns in the United States. See *e.g.*, *Direct Wholesale*, 67 FR 11, 654 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.*, 67 FR 9,997 (2002); *Denver Wholesale*, 67 FR 99,986 (2002).

On April 6, 2004, the State of Oklahoma enacted House Bill 2176. Among its provisions, the newly enacted legislation has designated pseudoephedrine tables as a Schedule V controlled substance under Oklahoma law. This provision further mandates that pseudoephedrine tablets sold only from licensed pharmacies and requires customers seeking to purchase this product to present photo identifications and sign for their purchases. As a result, it is presently prohibited under Oklahoma law for persons to sell pseudoephedrine tables from convenience stores or other non-pharmacy locations.

The Deputy Administrator's review of the investigative file reveals that on October 15, 2003, Mr. Osmani submitted an application for DEA Registration on behalf of OLW. OLW sought DEA registration as a distributor of the list I chemicals ephedrine and pseudoephedrine. OLW is a Limited Liability Corporation which became incorporated in Texas on October 23, 2003, and Mr. Osmani and his wife are the company's only employees.

On November 13, 2003, DEA diversion investigators conducted an on-site preregistration inspection at OLW's proposed registered location in

Denison, Texas. The location requested by OLW as a DEA-registered premise was a former gas station establishment. DEA's investigation revealed that in addition to its proposed registered location, Mr. Osmani owns the following Denison-area convenience stores. Lucky Liquor & Discount Tobacco; Lucky Stop #2; and, Lucky Stop #4. Mr. Osmani is also the owner of two Lucky Stop convenience stores located in Cartwright and Durant, Oklahoma. DEA's investigation revealed that as of January 2004, Cartwright, Oklahoma had an estimated population of 13,549. Each of Mr. Osmani's stores sell typical convenience store items including tobacco products, candy, automobile maintenance products and T-shirts.

Mr. Owmani informed DEA investigators that he would operate as a wholesale distributor to his five convenience stores, which he identified as his only customers. He further discussed plans to distribute certain listed chemical products, including Mini-Thin ephedrine tablets in six-count packets and 60-count bottles, as well as Max Brand pseudoephedrine products, also in six-count packets and 60-count bottles. Mr. Osmani estimated that these products would make up five to fifteen percent of OLW's total sales. Mr. Osmani further informed DEA investigators that OLW did not own any deliver trucks and employees from the two Oklahoma convenience stores would drive to OLW's Denison location to pick up list I chemical products for delivery to the Oklahoma business establishment.

According to the investigative file, as of July 1, 2003, distributors of pseudoephedrine products conducting business in Oklahoma were required to obtain a registration with the Director of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (the Bureau). 63 O.S. 2001, Section 2-302. DEA's investigation has revealed that as of January 7, 2004, neither Mr. Osmani nor OLW were registered with the Bureau to handle pseudoephedrine.

During the aforementioned onsite inspection by DEA, Mr. Osmani also informed investigators that his suppliers for listed chemicals were Silver Star and Import Warehouse, Incorporated, both of Dallas, Texas. However, when DEA investigators conducted verification checks with OLW's proposed suppliers on November 17, 2003, the owner of Import Warehouse stated that he would not be supplying listed chemicals products to OLW; and, the owner of Silver Star informed DEA personnel that he had planned to supply only