

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 tablets 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 tablets 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

ephedrine to OLW and not pseudoephedrine.

On November 19, 2003, DEA investigators requested purchase records from the two aforementioned establishments. The owner of Import Warehouse provided purchase records dating from May 23, 1998 to September 27, 2000, for sales of listed chemicals to two of Mr. Osmani's Denison-area convenience stores (Lucky Stop #2 and Lucky Stop #4). The records revealed that with the exception of July and August, 1998, Mr. Osmani ordered forty-eight, 60-count bottles of Mini 2 Way 200mg. Guaifenesin nearly every month during the above time period. In addition, Mr. Osmani ordered four cases (144 bottles per case) of Max Alert Pseudo (pseudoephedrine) 60-count in July 1998. One month later, Mr. Osmani ordered an additional 192 bottles of Max Alert Pseudo.

The owner of Silver Star also provided purchase records dating from April 24, 2001 to August 28, 2003, for the sale of listed chemical products to two of Mr. Osmani's Denison-area convenience stores (Lucky Liquor & discount Tobacco and Lucky Stop #4). The records revealed that on eleven separate occasions from November 8, 2001 to August 28, 2003, Mr. Osmani ordered a case (144 bottles per case) of 200-count Guaifensin 12.5mg; in April 2001 and again in November 2002, Mr. Osmani purchased 288 bottles of this product; on April 19, 2003, Mr. Osmani purchased 72 (60-count) bottles of Max Brand 2-Way ephedrine.

Pursuant to 21 U.S.C. 823(h), the Deputy Administrator may deny an application for 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 legitimate 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.*, ANM Wholesale, 69 FR 11,652 (2004); Energy Outlet, 64 FR 14269 (1999). *See also* Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

The Deputy Administrator finds factors one, two, four and five relevant to OLW's pending registration application.

With regard to factor one, maintenance of effective controls against diversion of listed chemicals into other than legitimate channels, the Deputy Administrator finds substantial evidence in the investigative file that OLW, through its owner Ty Osmani, has participated in the unlawful diversion of pseudoephedrine having reasonable cause to believe that it would be used to manufacture illicit methamphetamine. Mr. Osmani has purchased large quantities of pseudoephedrine and ephedrine products and distributed these products through his convenience stores located in Texas and Oklahoma. Prior to 2004, these areas have been known for their numerous seizures involving clandestine methamphetamine laboratories. In most instances, the primary sources for the diversion of these products are convenience stores and other "non-traditional retailers of over-the-counter drug products." Al-Alousi, Inc., 70 FR 3561 (2005). *See*, Sinbad Distribution, 67 FR 10232, 10233 (2002). Therefore, factor one weighs against the granting of OLW's pending application for registration.

With regard to factor two, compliance with applicable Federal, State, and local law, DEA's pre-registrant inspection revealed that as of July 1, 2003, distributors of pseudoephedrine products conducting business in Oklahoma were required to register with the state Bureau of Narcotics and Dangerous Drugs Control (the Bureau) pursuant to 63 O.S. 2001, Section 2-302. Mr. Osmani and OLW's failure to obtain state registration to handle listed chemicals is relevant under factor two, and also weighs against the granting of the pending application for registration.

With regard to factor four, past experience in the manufacture and distribution of chemicals, and factor five, such other factors relevant to and consistent with the public safety, the Deputy Administrator finds these factors relevant to Mr. Osmani and OLW's purchase of quantities of listed chemical products for distribution to,

and sale by his convenience stores in Texas and Oklahoma. These listed chemical products were for the most part, purchased by OLW on a monthly basis and appeared to be far in excess of the expected demand for such products. As noted in previous final orders, while there are no specific prohibitions under the Controlled Substance Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found that convenience stores constitute sources for the diversion of listed chemical products. Sinbad Distributing, *supra* at 10233; K.V.M. Enterprises, 67 FR 70968 (2002) (denial of application based in part upon information developed by DEA that the applicant proposed to sell listed chemicals to gas stations, and the fact that these establishments in turn have sold listed chemical products to individuals engaged in the illicit manufacture of methamphetamine).

DEA has found persuasive, expert testimony in the area of statistical analysis of convenience stores and their sale of pseudoephedrine. Branex, Inc., 69 FR 8,682 (2004); Express Wholesale, 69 FR 62086, 62088 (2004). In analyzing the expected sale of listed chemical products in the State of Oklahoma, a consultant in marketing information and databases offered expert testimony through the use of the 1997 United States Economic Census of Retail Trade and tabulated data which indicated 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. The marketing consultant characterized these five retail industries as "the traditional marketplace where such goods are purchased by ordinary customers." Express Wholesale, *supra*.

The market consultant also analyzed national data specific to the sale of over-the-counter, non-prescription drugs containing pseudoephedrine by convenience stores which he characterized as a "nontraditional market" for the sale of listed chemical products. He further determined " * * * 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." The marketing consultant concluded that "[c]onvenience stores, therefore, definitely constitute a 'non-traditional' market for the sale of over-the-counter, non-prescription drug pseudoephedrine products."

The marketing consultant further explained that this information support's DEA's conclusion that pseudoephedrine products distributed to this nontraditional market greatly exceeded the normal demand for such products at such retail outlets. He agreed that such excessive sales could be purchases of listed chemical products that were diverted to illicit uses. With respect to Oklahoma wholesale pseudoephedrine sales of several distributors and over 300 of their retail customers, all of which were convenience stores, a July 2002 analysis by the marketing consultant led to the conclusion "that without evidence of the existence of immense numbers of legitimate customers, it was likely that the massive inventories of pseudoephedrine products purchased by these Oklahoma stores were being turned to illegal uses." *Express Wholesale, supra*.

With respect to the instant matter, Mr. Osmani and OLV have similarly amassed large quantities of pseudoephedrine and ephedrine products. The frequency and quantity of listed chemicals purchased by OLV from 1998 to 2003 defined all available and conventional marketing data for the expected sale of these products. Given the demonstrated lack of legitimate demand for these products when sold from convenience stores, the Deputy Administrator is left with the conclusion that Mr. Osmani and OLV purchased pseudoephedrine and ephedrine products for sale to individuals involved in the illicit manufacture of methamphetamine.

As noted above, effective April 6, 2004, Oklahoma enacted House Bill 2176, titled the "Oklahoma Methamphetamine Reduction Act of 2004." This provision includes the requirement that the sale of pseudoephedrine tablets are now restricted to licensed pharmacies. As in a prior DEA final order, the Deputy Administrator finds in the instant matter that OLV's proposed distribution of listed chemicals through its convenience stores is no longer legally viable in Oklahoma. See, *Express Wholesale, supra* at 62089.

A review of early data for 2004 reveals that the newly enacted laws have resulted in an apparent reduction in the number of seizures involving clandestine methamphetamine labs in Oklahoma. These developments in Oklahoma are encouraging and represent another important step in the ongoing battle to curb methamphetamine abuse in the United States. In keeping with this positive trend, DEA must also act in an

appropriate fashion to ensure that listed chemicals are not diverted. The Deputy Administrator notes that while Mr. Osmani and OLV seek DEA registration in the State of Texas, the company also seeks to distribute listed chemicals from convenience stores located in Oklahoma. Based solely on the population statistics of Cartwright and Durant, Oklahoma, it would appear at first glance that the market for over-the-counter drug products in these cities is relatively insignificant. However, as the record before the Deputy Administrator clearly demonstrates, the relatively small size of the Oklahoma markets serviced by OLV is not a significant factor since Mr. Osmani appears intent on purchasing extraordinarily large quantities of listed chemical products without regard to market size. These purchasing practices indicate that OLV would willingly accommodate persons involved in the illicit methamphetamine trade. Based on the foregoing, the Deputy Administrator concludes that granting the pending application of OLV 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 DEA Certificate of Registration, previously submitted by Tysa Management, d.b.a. Osmani Lucky Wholesale be, and it hereby is, denied. This order is effective April 14, 2005.

Dated: February 24, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

James S. Bischoff, M.D.; Revocation of Registration

On June 28, 2004, the Deputy Administrator, Drug Enforcement Administration (DEA), issued an Order to Show Cause/Immediate Suspension of Registration to James S. Bischoff, M.D. (Dr. Bischoff) who was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration BB0377247 under 21 U.S.C. 824(a)(4) and deny any pending applications for renewal or modification of that registration under 21 U.S.C. 823(f). Dr. Bischoff was further notified that his registration was being immediately suspended under 21

U.S.C. 824(d) as an imminent danger to the public health and safety.

The Order to Show Cause alleged in relevant part, that Dr. Bischoff diverted controlled substances through larceny and fraudulent prescriptions, failed to maintain required records, could not account for 32,000 dosage units of controlled substances and dispensed controlled substances to individuals without a bona fide doctor-patient relationship or legitimate medical purpose. The Order to Show Cause also notified Dr. Bischoff that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

On July 14, 2004, a DEA investigator personally served the Order to Show Cause/Immediate Suspension of Registration on Dr. Bischoff at the offices of the Ennis, Montana Police Department. Since that date, DEA has not received a request for a hearing or any other reply from Dr. Bischoff or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since personal delivery of the Order to Show Cause/Immediate Suspension of Registration to the registrant and (2) no request for hearing having been received, concludes that Dr. Bischoff is deemed to have waived his hearing right. See David W. Linder, 67 FR 12579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Dr. Bischoff is registered with DEA as a practitioner under Certificate of Registration BB0377247. Dr. Bischoff's registered location is also his residence, which is located in Ennis, Montana.

In April 2003, Dr. Bischoff took "Patient B," a 16-year-old high school student, to an out of town physician specialist for emergency treatment after the boy's had was cut in an accident. Dr. Bischoff was a friend of the boy's father and step-mother and would come to their home for social visits/dinners. They were both out of town at the time of the accident and Dr. Bischoff volunteered to take the boy to the specialist. While the specialist did not recommend any treatment with controlled substances, Dr. Bischoff wrote the boy a prescription for 100 tablets of Oxycontin, a Schedule II narcotic controlled substance, which he personally picked up a local pharmacy. However, he delivered only 20 tablets to the boy, unlawfully diverting the