

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 14269 (1999). *See also, Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

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

With regard to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant based on Mr. Patel'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 products has been a factor in denying pending applications for registration. *See, e.g., Direct Wholesale, supra*, 69 FR 11654; *ANM Wholesale*, 69 FR 11652 (2004); *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002).

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor weighs heavily 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 decisions, have been identified as constituting the grey market for list I chemical products. It is apparent that Prachi intends on being a participant in this market.

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 11652; *Xtreme Enterprises, Inc., supra*, 67 FR 76195; *Sinbad Distributing*, 67 FR 10232 (2002); *K.V.M. Enterprises*, 67 FR 70968 (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 76197. As in *Xtreme Enterprises, Inc.*, Mr. Patel's lack of a criminal record and stated 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 grey market.

The Deputy Administrator is further troubled by Mr. Patel's reticence to provide requested information to DEA, indicating his company cannot be trusted to handle the 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 823 and 28 CFR 0.100(b) and 0.104, hereby orders the pending application for DEA Certificate of Registration, previously submitted by Prachi Enterprises, Inc., be, and it hereby is, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### **Volusia Wholesale; Denial of Registration**

On July 23, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Volusia Wholesale (Volusia) proposing to deny its December 12, 2003, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting Volusia's application would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h). The order also notified Volusia that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to Volusia at its then-proposed registered location at 917 Daytona Avenue, Daytona Beach,

Florida 32117. It was received on August 2, 2004, and DEA has not received a request for a hearing or any other reply from Volusia or anyone purporting to represent the company in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days have passed since delivery of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Volusia has waived its hearing right. *See Aquil Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53(c) and (d) and 1316.67. 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). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. As noted 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 11654 (2004); *Branex, Inc.*, 69 FR 8682 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.*, 67 FR 9997 (2002); *Denver Wholesale*, 67 FR 99986 (2002).

The Deputy Administrator's review of the investigative file reveals that on or about September 9, 2003, an application was submitted by the owner of Volusia, Mr. Anwar Khrino, seeking registration to distribute ephedrine and pseudoephedrine list I chemical products. The application initially listed the proposed registered location as Mr. Khrino's then-residence, 1420 N. Grandview Avenue, Daytona Beach, Florida 32118. He subsequently moved to 917 Daytona Avenue, Daytona Beach, Florida 32117, which was to be Volusia's registered address.

In connection with the pending application, an on-site pre-registration investigation was conducted at the Daytona Avenue proposed premises. The location was Mr. Khrino's residence. There were no security measures in place and his intent was to store the chemical products overnight in a locked delivery van in the driveway.

Mr. Khrino advised investigators Volusia is a sole proprietorship and wholesale distributor of approximately 60 to 80 sundry and novelty items to convenience stores and gas stations. He proposed to distribute "two packs" of

six different cough and cold remedies containing pseudoephedrine.

Mr. Khrino identified two proposed suppliers of listed chemicals, one of which DEA was aware no longer held a DEA registration to handle listed chemicals. Mr. Khrino initially failed to provide DEA a complete proposed customer list for listed chemical products. Later, he sent DEA a handwritten list of 13 purported customers for listed chemicals. DEA conducted two verifications of purported customers. At the first convenience store, investigators were told the store was not a customer of Volusia. Investigators also noted the store was displaying the combination ephedrine, Mini-thins product on its counter. Investigators were unable to locate the second purported customers, a delicatessen. There was no such retailer at the address provided by Mr. Khrino and the contact number for this "customer" turned out to be Volusia's fax machine.

The State of Florida has a substantial methamphetamine abuse problem in Northeast and Central Florida, and DEA is aware of a past history of trafficking in precursors in these areas. Distributors or retailers serving in the illicit methamphetamine trade observe no borders and trade across state lines. In fact, where precursor laws are stringent, out-of-state distributors often make direct shipments to retailers without observing state requirements.

DEA is aware that small illicit laboratories operate with listed chemical products often procured, legally or illegally, from non-traditional retailers of over-the-counter drug products, such as gas stations and small retail markets. Some retailers acquire product from multiple distributors too mask their acquisition of large amounts of listed chemicals. In addition, some individuals utilize sham corporations or fraudulent records to establish a commercial identity in order to acquire listed chemicals.

In the adjacent State of Georgia, there has been a consistent increase in the number of illicit laboratories and enforcement teams continue to note a trend toward smaller capacity laboratories. This is likely due to the ease of concealment associated with smaller laboratories, which continue to dominate seizures and cleanup responses.

DEA knows by experience that there exists a "gray market" in which certain high strength, high quantity pseudoephedrine and ephedrine products are distributed only to convenience stores and gas stations, from where they have a high incidence

of diversion. These grey market products are not sold in large discount stores, retail pharmacies or grocery stores, where sales of therapeutic over-the-counter drugs predominate. Mini-Thins and "two-way" products and other pseudoephedrine products are prime products in this gray market industry and are rarely found in any retail store serving the traditional therapeutic market.

DEA also knows from industry data, market studies and statistical analysis that over 90% of over-the-counter drug remedies are sold in drug stores, supermarket chains and "big box" discount retailers. Less than one percent of cough and cold remedies are sold in gas stations or convenience stores. Studies have indicated that most convenience stores could not be expected to sell more than \$20.00 to \$40.00 worth of products containing pseudoephedrine per month. The expected sales of ephedrine products are known to be even smaller. Furthermore, convenience stores handling gray market products often order more product than what is required for the legitimate market and obtain chemical products from multiple distributors.

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. Section 823(h) requires that 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 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.

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 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 14269 (1999). *See also,*

*Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (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 DEA pre-registration inspection documented inadequate security at the proposed registered location, which is a personal residence. *See, e.g., John E. McRae d/b/a J & H Wholesale*, 69 FR 51480, 51481 (2004). Mr. Khrino has proposed the storage of listed chemical products inside a van that is routinely parked in the driveway of his residence. As the Deputy Administrator has previously held, "the prospect of listed chemicals being stored in an unattended vehicle [is] fraught with the dangers of diversion." *See, William E. "Bill" Smith d/b/a B & B Wholesale*, 69 FR 22559, 22560 (2004). Accordingly, this factor weighs against the granting of Volusia's pending registration 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 Mr. Khrino'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 products has been a factor in denying pending applications for registration. *See, e.g., Direct Wholesale, supra*, 69 FR 11654; *ANM Wholesale*, 69 FR 11652 (2004); *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002).

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor weighs heavily against granting the application. Unlawful methamphetamine use is a growing public health and safety concern throughout the United States and the 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 decisions, have been identified as constituting the grey market for list I chemical products. It is apparent that Volusia intends on being a participant in this market.

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 11652; *Xtreme Enterprises, Inc., supra*, 67 FR 76195; *Sinbad Distributing*, 67 FR 10232 (2002); *K.V.M. Enterprises*, 67 Fr 70968 (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 76197. As in *Xtreme Enterprises, Inc.*, Mr. Khrino's lack of a criminal record and 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.

The Deputy Administrator is further troubled by Mr. Khrino's failure to provide accurate information to DEA, indicating his company cannot be trusted to handle the 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 Volusia Wholesale, be, and it hereby is, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF LABOR

### Employment and Training Administration

#### State Quality Service Plan (SQSP); Comment Request

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden

conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with a provision of the Paperwork Reduction Act of 1995 at 44 U.S.C. 3506(c)(2)(A). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration (ETA) is soliciting comments concerning the proposed extension of the State Quality Service Plan (SQSP).

Guidelines for completion and submittal of the SQSP are contained in ETA Handbook 336, 17th Edition. Fiscal year-specific information such as Federal program emphasis, or additional budget allocations, will be provided annually in an implementation directive that will initiate the planning process each year. The requirements of the reporting and data collection process itself will remain unchanged from year to year. Copies of the SQSP Handbook may be obtained by contacting the addressee below. The Handbook is also available on the Internet at <http://www.workforcesecurity.doleta.gov>.

**DATES:** Submit comments on or before January 28, 2005.

**ADDRESSES:** Send comments to Delores A. Mackall, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S-4231, Washington, DC 20210, (202) 693-3183 (this is not a toll-free number); fax, (202) 693-3975; Internet: [mackall.delores@dol.gov](mailto:mackall.delores@dol.gov).

**FOR FURTHER INFORMATION CONTACT:** Delores A. Mackall, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S-4231, Washington, DC 20210, (202) 693-3183 (this is not a toll-free number); fax, (202) 693-3975; Internet: [mackall.delores@dol.gov](mailto:mackall.delores@dol.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The SQSP is the planning instrument for the Unemployment Insurance (UI) system nationwide. The statutory basis for the SQSP is Title III of the Social Security Act, which establishes conditions for each State to receive grant funds to administer its UI program. Plans are prepared annually, since funds for UI operations are appropriated each year. ETA's annual budget request for State UI operations contains workload assumptions for

which a State must plan in order for the Secretary of Labor to carry out her responsibilities under Title III. ETA issues financial planning targets based on the budget request. States make plans based on these assumptions and targets.

##### II. Desired Focus of Comments

Currently, the Department of Labor is soliciting comments concerning the proposed extension collection of the UI SQSP. The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submission of responses.

A copy of the proposed ICR can be obtained by contacting the office listed above in the addressee section of this notice.

##### III. Current Actions

ETA proposes to extend this clearance which contains a reduction in burden hours. The reduction in hours is a result of changes to the SQSP which stemmed from a 5-year review of UI Performs. The number of measures for which a state is held accountable has been reduced; however, the average number of corrective action plans that states must submit for not meeting the criteria has increased. States are no longer required to submit continuous improvement plans. The SQSP narrative has been streamlined to exclude previously required Focus narratives. Additionally, states will no longer be required to address environmental factors, such as economic conditions, political climate, labor/business relationships, or state legislative issues. States will describe in a single narrative: performance in comparison to the Government Performance Results Act (GPRA) goals; results of customer satisfaction surveys, which is optional; and actions planned to correct deficiencies regarding program reviews,