

suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- 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 agencies 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.

Overview of This Information Collection

(1) Type of Information Collection: Extension of a currently approved collection.

(2) Title of the Form/Collection: Report of Theft or loss of Controlled Substances—DEA form 106.

(3) Agency form number, if any, and the applicable component of the Department sponsoring the collection: Form Number: DEA Form 106. Office of Diversion Control, Drug Enforcement Administration, Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. Other: Not-for-profit, State, local or tribal government. Title 21 CFR 1301.74(c) and 1301.76(b) require DEA registrants to complete and submit a DEA-106 upon discovery of a theft or significant loss of controlled substances. This provides accurate accountability and allows DEA to monitor substances diverted for illicit purposes.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: DEA estimates that 5,659 registrants submit 8,310 forms annually for this collection. DEA estimates that each response takes 30 minutes.

(6) An estimate of the total public burden (in hours) associated with the collection: DEA estimates that this collection has a public burden of 4,155 hours annually.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: January 14, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04-32]

Al-Alousi, Inc., Denial of Registration

On March 16, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Al-Alousi, Inc. (AAI) proposing to deny its March 31, 2003, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting AAI's application 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 AAI at its proposed registered location at 8760 Greenwell Springs Road, Baton Rouge, Louisiana. On April 14, 2004, AAI's owner, Mr. Humam Al-Alousi, requested a hearing and on April 26, 2004, Administrative Law Judge Mary Ellen Bittner ordered the parties to file prehearing statements by June 7, 2004. This date was later extended until August 24, 2004. As a result of AAI's failure to file a prehearing statement, Judge Bittner considered its hearing right to have been waived and issued an Order Terminating Proceedings on September 3, 2004. The investigative case file was then forwarded to the Deputy Administrator for a final order pursuant to 21 CFR 1301.46.

The Deputy Administrator finds that AAI has waived its hearing right and after considering relevant material from the investigative file, 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 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).

The Deputy Administrator's review of the investigative file reveals that AAI's president is Mr. Al-Alousi and his wife, Lois Al-Alousi, is vice-president. On or about March 31, 2003, an application was submitted by Mrs. Al-Alousi on behalf of AAI, seeking registration to distribute ephedrine and pseudoephedrine list I chemical products. Subsequently, AAI advised DEA that its application would only be for a registration to distribute pseudoephedrine products.

In connection with the pending application, an on-site pre-registration investigation was conducted at the proposed registered location in May 2003. Mr. Al-Alousi represented to investigators that he had purchased AAI in December 2002 and the company had previously done business at that location under a different name and owner.

The investigators' review showed that a prior DEA investigation of the former company and its owner had been conducted which adduced substantial information that the company had distributed list I chemicals without a DEA registration and knowingly distributed large quantities of list I chemicals to methamphetamine laboratories during the mid-to-late 1990's. The former owner, a citizen of Lebanon, had been arrested by U.S. Immigration and Naturalization Service officers for willfully and falsely representing himself as a citizen of the United States.

At the time of the DEA investigators' on-site pre-registration inspection of AAI's premises, the business sign still bore the former company's name and that name was also on a facsimile cover sheet and document which was sent by Mrs. Al-Alousi to DEA investigators during the pre-registration inquiry.

Mr. Al-Alousi advised investigators that AAI was now a wholesale distributor of cigarettes, washing powder, oil, candy and novelty items to approximately 150 convenience stores

and restaurants in the Baton Rouge area. He stated that all 150 of AAI's customers would be purchasing list I chemicals. In addition to its wholesale business, AAI operated a convenience store at the proposed registered address and many of its customers came to that location to pick up purchases at a check out counter. Given the facility's set-up, AAI's wholesale and retail customers and all of its employees would have physical access to the areas where the listed products would be stored.

During the investigation, the Al-Alousi's were unable to provide investigators any records of sales and purchases and stated their records were transferred weekly to a bookkeeper. According to a list provided investigators, the great majority of AAI's customers were convenience stores and gas stations. It was also determined that neither Mr. nor Mrs. Al-Alousi had any prior experience in the distribution of list I chemicals.

On July 9, 2003, investigators attempted to conduct verifications of twelve customers from AAI's list. Two addresses did not exist; one was a printing shop that was out of business; one was an apartment complex; one was a bar/pool hall; one was a fast-food stand; two alleged customers advised they had never done business with either AAI or its predecessor company; two others stated they only purchased paper and plastic products from its predecessor company and had never heard of AAI; and one stated he had purchased list I chemical cold products from AAI's predecessor but would not do so in the future and had never heard of AAI. The results of these verification attempts cast doubt on the veracity of Mr. Al-Alousi's representations regarding the nature of AAI's business and its prospective customers for list I chemical products.

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 to 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.

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.

DEA also knows from industry data, market studies and statistical analysis that over 90 percent 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 14,259 (1999). *See also,* Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1999).

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 that many of AAI's customers would be coming to the registered location to pick up their products. Under this procedure, AAI would not be able to adequately verify the location and legitimacy of its customers. Additionally the listed chemicals would be stored such that AAI's retail and wholesale customers, as well as all of its employees, would have access to the listed chemical products, thus increasing risk of diversion. Accordingly, this factor weighs against the granting of AAI's 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 Mr. and Mrs. Al-Alousi's lack of knowledge and experience regarding the laws and regulations governing handing 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 11,654; ANM Wholesale, 69 FR 11,652 (2004); Xtreme 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 weighs heavily against granting the application. Unlawful methamphetamine use is a growing public health and safety concern throughout the United States and the South. 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 AAI 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 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. As in Xtreme Enterprises, Inc., Mr. and Mrs. Al-Alousi’s lack of a criminal record and stated intent to comply with the law and regulations are far outweighed by their lack of experience and the company’s intent to sell pseudoephedrine products almost exclusively to the grey market.

The Deputy Administrator is also troubled by AAI’s failure to provide accurate customer information to DEA investigators, indicating the company cannot be trusted to handle the responsibilities of a registrant. Further, its continued or implied use of its predecessor’s name, an entity which prior investigations had linked with the diversion of listed chemicals to illicit laboratories, raises questions about AAI’s customer base and the risk that its products might be sold to previous customers of AAI’s predecessor and then diverted to illegal purposes.

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, submitted by Al-Alousi, Inc., be, and it hereby is, denied. This order is effective February 24, 2005.

Dated: December 30, 2004.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ray V. Surapaneni, D.O.; Revocation of Registration

On April 29, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Ray V. Surapaneni, D.O. (Dr. Surapaneni) who was notified of an opportunity to show cause as to why DEA should not revoke his DEA

Certificate of Registration, BS3724932, pursuant to 21 U.S.C. 824(a)(3). Specifically, the Order to Show Cause alleged that Dr. Surapaneni’s authority to handle controlled substances in the State of Missouri had been revoked.

The Order to Show Cause notified Dr. Surapaneni that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived. Alternatively, he could waive a hearing and submit a written statement regarding his position on the matters of fact and law for the Deputy Administrator’s consideration, along with the material within the investigative case file.

The Order to Show Cause was initially sent by certified mail to Dr. Surapaneni at an address which was not current. On September 2, 2004, the Order to Show Cause was resent and Dr. Surapaneni received it on September 6, 2004. In his September 10, 2004, letter to the Hearing Clerk, DEA Office of Administrative Law Judges, Dr. Surapaneni affirmatively waived a hearing and asked the Deputy Administrator to not revoke his registration and to consider the contents of the letter in deciding the matter.

The Deputy Administrator of DEA, after considering material from the investigative file and the written statement of Dr. Surapaneni, now enters her final order without a hearing pursuant to 21 CFR 1301.43(b) and (e) 1301.46.

The Deputy Administrator finds Dr. Surapaneni is currently registered with DEA as a practitioner authorized to handle controlled substances in Schedules II through V under DEA Certificate of Registration BS3724932, with a registered location of 1515 Union Avenue, Moberly, Missouri.

According to information in the investigative file, in June 2003, Dr. Surapaneni entered into a Memorandum of Agreement (MOA) with the DEA Saint Louis Field Division as a condition of renewing his DEA registration. Among the MOA’s terms was a provision that his DEA registration would terminate automatically if he were to lose authority to handle controlled substances in Missouri, his State of registration.

On December 9, 2003, the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) notified Dr. Surapaneni that his Missouri Controlled Substances Registration No. 307766793, had been terminated and he did not “currently have the authority to conduct any activities with controlled substances in the state of Missouri.” The investigative file indicates his state controlled

substances registration was terminated because it had been issued for a specific location in Paris, Missouri and, pursuant to a March 11, 2003, Settlement Agreement Between Dr. Surapaneni and BNDD, his registration would terminate immediately if he relocated his professional practice. BNDD subsequently discovered Dr. Surapaneni had never been employed by or practiced at the Paris, Missouri location. Efforts by DEA diversion investigators to obtain his certificate by surrender proved unsuccessful and show cause proceedings were then initiated.

In his written statement to the Deputy Administrator, Dr. Surapaneni indicates he was unable to join the Paris, Missouri, practice because he lacked start-up funds, attributing this financial plight to a previous office manager having embezzled \$150,000 from him. Dr. Surapaneni also says he is seeking medical employment and intends to reapply for his Missouri registration once he has found a position.

However, Dr. Surapaneni does not dispute that his State controlled substances registration was terminated by BNDD or claim any current authority to handle controlled substances in that State. Therefore, the Deputy Administrator finds Dr. Surapaneni is currently not authorized to handle controlled substances in Missouri.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without State authority to handle controlled substances in the State in which he conducts business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See *Richard J. Clement, M.D.*, 68 FR 12, 103 (2003); *Dominick A. Ricci, M.D.*, 58 FR 51,104 (1993); *Bobby Watts, M.D.*, 53 FR 11,919 (1988).

Here, it is clear Dr. Surapaneni’s State controlled substance registration was terminated and there is no information that action was ever stayed or that his registration has been reinstated. As a result, Dr. Surapaneni is not licensed to handle controlled substances in Missouri, where he is registered with DEA. Therefore, he is not entitled to maintain that registration.

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 C.F.R. 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, BS3724932, issued to Ray V. Surapaneni, D.O., be, and it hereby is, revoked. The Deputy Administrator further orders that any