

45075, July 28, 2004). Notice of the scheduling of the Commission's review and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on July 28, 2004 (69 FR 45075). Notice of cancellation of the public hearing scheduled in connection with this review (due to lack of interest) was published in the **Federal Register** on December 7, 2004 (69 FR 70705). Notice of the revised scheduling of the review was published in the **Federal Register** on January 28, 2005 (70 FR 4150).

The Commission transmitted its determination in this review to the Secretary of Commerce on May 11, 2005. The views of the Commission are contained in USITC Publication 3775 (May 2005), entitled *Sebacic Acid from China: Investigation No. 731-TA-653 (Second Review)*.

Issued: May 11, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05-9839 Filed 5-17-05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

A-1 Distribution Wholesale; Denial of Registration

On October 8, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to A-1 Distribution Wholesale (A-1) proposing to deny its September 19, 2002, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting A-1'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 A-1 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 A-1 at its proposed registered location at 6751 Macon Road, Suite 18, Columbus, Georgia 31909. It was then forwarded by the U.S. Postal Service to A-1's new address at 7565 Chattsworth Road, Midland, Georgia 31820-4026, where it was received on October 18, 2004. DEA has not received a request for a hearing or any other reply

from A-1 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 A-1 has waived its hearing right. *See* *Aqui Enterprises*, 67 FR 12,576 (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 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 on or about September 19, 2002, an application was submitted by the owner of A-1, Mr. David Smith, seeking registration to distribute ephedrine and pseudoephedrine list I chemical products. The application originally included phenylpropanolamine, but that listed chemical product was eventually deleted from the request.

In connection with the pending application, an on-site pre-registration investigation was conducted at the proposed premises in April 2003. Investigators were advised that A-1 was a sole proprietorship, operated by Mr. Smith and his wife, with no other employees. It commenced operations in June 2002 and was a wholesale distributor of general merchandise such as health and beauty aids, automotive products, sunglasses and other sundry items. A-1 provided a list of products it intended to carry which included 60 tablet bottles of Mini Two Way and Two Way brand combination ephedrine, as well as Pseudo 60 brand pseudoephedrine. The majority of A-1's proposed customers were gas stations, small retail markets and convenience stores in the Columbus, Georgia area. Neither Mr. Smith nor his wife had any

prior experience with the distribution of list I chemicals.

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.

The Deputy Administrator has previously found that the illegal production of methamphetamine continues unabated within the DEA Atlanta region. The adjacent State of Tennessee leads the region in the number of clandestine laboratories seized, accounting for approximately 50 percent of the clandestine laboratories seized during the second quarter of 2002. When compared with the third quarter of 2001, the increase in clandestine laboratory seizures is notable. According to later records for the Atlanta region, 360 clandestine laboratories were seized during the third quarter of 2002. Of the 360 laboratories seized during that reporting period, 207 were located in Tennessee, 103 in Georgia, 35 in South Carolina and 15 in North Carolina. *See* *CWK Enterprises, Inc. (CWK)*, 69 FR 69,400 (2004); *Prachi Enterprises, Inc. (Prachi)*, 69 FR 69,407 (2004).

In the 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. The adjacent State of Tennessee also has a substantial methamphetamine abuse problem in the Chattanooga and Eastern Tennessee areas and DEA is aware of a past history of trafficking in precursors in these locations. Distributors or retailers selling 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 retainers without observing state requirements. *See* *CKW, supra*, 69 FR 69,400; *Prachi, supra*, 69 FR 69,407.

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. "Two-way" ephedrine and single entity 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. Most 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 of 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 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. and Mrs. Smith'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.,* CWK, *supra*, 69 FR 69,400; Prachi, *supra*, 69 FR 69,407; 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 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 A-1 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., 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., lack of a criminal record and intent to

comply with the law and regulations are far outweighed by A-1's lack of experience and the company's intent to sell ephedrine and pseudoephedrine primarily to the gray market. *See also,* CWK, *supra*, 69 FR 69,400; Prachi, *supra*, 69 FR 69,407.

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 A-1 Distribution Wholesale, be, and it hereby is, denied. This order is effective June 17, 2005.

Dated: May 9, 2005.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Robert A. Burkich, M.D.; Revocation of Registration

On August 23, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Robert A. Burkich, M.D. (Dr. Burkich) of Nashville, Tennessee, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration BB4812043, as a practitioner, under 21 U.S.C. 824(a)(3) and deny any pending applications for renewal or modification of that registration pursuant to 21 U.S.C. 823(f). As a basis for revocation, the Order to Show Cause alleged that Dr. Burkich is not currently authorized to practice medicine or handle controlled substances in Tennessee, his state of registration and practice.

On September 15, 2004, Dr. Burkich, acting *pro se*, filed a Waiver of Hearing and Written statement (Written Statement) with the Hearing Clerk of the DEA Office of Administrative Law Judges. The investigative file and Written Statement were then forwarded to the Deputy Administrator for her final order.

The Deputy Administrator finds Dr. Burkich waived his right to a hearing and, in lieu of a hearing, submitted a Written Statement regarding his