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.

[FR Doc. 05–9833 Filed 5–17–05; 8:45 am]

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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 than 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

position on the matters of fact and law that are involved in this proceeding. Accordingly, after considering material from the investigative file and Dr. Burkich's Written Statement, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(c) and (e) and 1301.46.

The Deputy Administrator finds Dr. Burkich currently possesses DEA Certificate of Registration BB4812043, which expires on July 31, 2005. The Deputy Administrator further finds that on March 17, 2004, Tennessee Board of Medical Examiners (Tennessee Board) issued a Final Order revoking Dr. Burkich's license to practice medicine in Tennessee. The Tennessee Board's action was based upon its findings of fact that Dr. Burkich had been convicted in the United States District Court for the Eastern District of Tennessee of one felony count of mail fraud (18 U.S.C. 1341) and that the Georgia Composite State Board of Medical Examiners (Georgia Board) had revoked Dr. Burkich's license to practice medicine in Georgia, as a result of that conviction.

In his Written Statement, Dr. Burkich concedes he pled guilty to the criminal charge. However, he alleges he had a viable defense of entrapment and only pled guilty after being misadvised by his retained defense counsel who, Dr. Burkich asserts, was ineffective and had a conflict of interest. Attached to his Written Statement is a Motion for a Certificate of Appealability, which Dr. Burkich filed in the United States Court of Appeals for the Sixth Circuit (Case No. 04–6027). In that Motion, Dr. Burkich asserts in detail the factual and legal basis for the claims in his Written Statement.

The Deputy Administrator has determined that on November 23, 2004, the court of Appeals issued an Order denying Dr. Burkich's Motion for a Certificate of Appealability. He subsequently filed a Petition for an En Banc Rehearing which has not yet been acted upon by the Court. Accordingly, the federal conviction which was the underlying basis for Dr. Burkich's license revocation remains a valid judgment.

More significantly for purposes of this proceeding, Dr. Burkich does not contend in either his Written Statement or the accompanying Motion, that the Tennessee Board's Final Order has been stayed, modified or terminated or that either of his state medical licenses have been reinstated. Further, there is no evidence in the investigative file indicating the Tennessee Board's Final Order is no longer in effect.

Therefore, the Deputy Administrator finds Dr. Burkich is not currently authorized to practice medicine in the States of Tennessee and Georgia. As a result, it is reasonable to infer he is also without authorization to handle controlled substances in either state.

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 Stephen J. Graham, M.D., 69 FR 11661 (2004); Dominick A. Ricci, M.D., 58 FR 51104 (1993); Bobby Watts, M.D., 53 FR 11919 (1988).

Here, it is clear Dr. Burkich's Tennessee medical license has been revoked and he is not currently licensed to handle controlled substances in that state, where he is registered with DEA. Therefore, he is not entitled to a DEA registration in Tennessee.

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 that DEA Certificate of Registration BB4812043, issued to Robert A. Burkich, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, 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

Salvatore DeFrank, D.P.M. Revocation of Registration

On October 28, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Salvatore DeFrank, D.P.M. (Dr. DeFrank) of Dallas, Texas. Dr. DeFrank was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, BD8259346, as a practitioner, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for reason that his continued registration would be inconsistent with the public interest. Dr. DeFrank was further notified that his DEA registration was immediately suspended as an imminent danger to the public health and safety pursuant to 21 U.S.C. 824(d).

The Order to Show Cause and Immediate Suspension of Registration alleged in sum, that Dr. DeFrank was illegally prescribing controlled substances over the Internet without personal contacts, examinations or bona fide physician/patient relationships with the customers ordering the medications. These prescriptions were not issued ''in the usual course of professional treatment'' and violated 21 CFR 1306.04 and 21 U.S.C. 841(a).

According to the investigative file, the order to Show Cause and Immediate Suspension of Registration was personally accepted on Dr. DeFrank's behalf by his attorney in Carrolltown, Texas, on November 4, 2004. More than thirty days have passed since service of the Order to show Cause and Immediate Suspension of Registration and DEA has not received a request for hearing or any other reply from Dr. DeFrank or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause and Immediate Suspension of Registration to Dr. DeFrank's attorney, and (2) no request for hearing having been received, concludes that Dr. DeFrank 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.

While some consumers use Internet pharmacies for convenience, privacy and cost savings, others, including minor children, use the anonymity of the Internet to procure controlled substances illegally. The role of a legitimate online pharmacist is to dispense prescription medications and to counsel patients about the proper use of these medications, not to write or originate prescriptions. Internet profiteers are online suppliers of prescription drugs, be they owners, operators, pharmacists, or doctors, who illegally and unethically market controlled substances via the Internet for quick profit. Operation PHARMNET, which this Order to show Cause and Immediate Suspension of Registration is a part of, is a nationwide action by the DEA to disrupt and dismantle this illegal and dangerous cyberspace threat to the public health and safety.