Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–9250 Filed 5–9–05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jay Enterprises of Spartanburg, Inc.; Denial of Registration

On September 28, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Jay Enterprises of Spartanburg, Inc. (Jay Enterprises/Respondent) proposing to deny its January 15, 2004, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting Respondent'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 Jay Enterprises that should no request for a hearing be filed within 30 days, it hearing right would be deemed waived.

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to Respondent at its address of record at 136 Belvedere Drive, Spartanburg, South Carolina 29301. A notice of receipt was signed on behalf of Jay Enterprises and returned to DEA on October 26, 2004. DEA has not received a request for a hearing or any other reply from Jay Enterprises 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 Jay Enterprises 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 which are legitimately manufactured and distributed in single entity and combination forms as decongestants and bronchodilators, respectively. Both are used as precursor chemicals in the illicit manufacture of methamphetamine and amphetamine.

Phenylpropanolamine, also a list I chemical, is a legitimately manufactured and distributed product used to provide relief of symptoms from inflammation of the sinus, nasal and upper respiratory tract tissues and for weight control. Phenylpropanolamine is also used as a precursor in the illicit manufacture of methamphetamine and amphetamine. In November 2000, the United States Food and Drug Administration (FDA) issued a public health advisory requesting that drug companies discontinue marketing products containing phenylpropanolamine and that consumers not use them, due to risk of hemorrhagic stroke. As a result, many pharmaceutical companies have stopped using phenylpropanolamine as an active ingredient and, based on FDA's findings, DEA has determined that a request to distribute phenylpropanolamine constitutes a basis for denial of an application for DEA registration. See, e.g., Gazaly Trading, 69 FR 22561 (2004); Shani Distributors, 68 FR 62234 (2003).

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); Denver Wholesale, 67 FR 99986 (2002); Yemen Wholesale Tobacco and Candy Supply, Inc., 67 Fr 9997 (2002).

The Deputy Administrator's review of the investigative file reveals that on or about January 15, 2004, an application was submitted by the President and sole employee of Jay Enterprises, Mr. Desai S. Devangkumar, seeking registration to distribute ephedrine, pseudoephedrine and phenylpropanolamine listed chemical products. In connection with the pending application, an on-site pre-registration investigation was conducted by DEA Diversion Investigators at the proposed registered location, which turned out to be Mr. Devangkumar's residence. There were no security measures in place there and he stated he would store the listed chemicals in a rental unit at a nearby storage facility. Neither location afforded adequate physical security for storage of listed chemicals, as required by 21 CFR 1309.71.

Mr. Devangkumar advised investigators his company distributed sundries to retailers and that customers had requested that it carry list I chemical products. Other than the two brands which were specifically requested by customers, ''Max Brand'' and ''Mini-Thins,'' he was unable to identify any other products he intended to carry if registered. Mr. Devangkamur also had no prior experience with list I chemical and was unaware they were used as precursors in illicitly manufacturing methamphetamine. While unable to provide a list of specific customers, Mr. Devangkumar advised he planned to sell list I chemical products to area convenience stores and truck stops.

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 convenience stores. 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.

Throughout the Southeastern United States, 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 small 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 rarely sold in large discount stores, retail pharmacies or grocery stores, where sales of therapeutic over-the-counter drugs predominate.

Max Brand has previously been identified by DEA as the ''precursor product predominantly encountered and seized at clandestine methamphetamine laboratories'' and that ''[c]onvenience stores are the primary source for the purchase of the Max Brand products, which are the preferred brand for use by illicit methamphetamine producers, and users.'' Express Wholesale, 69 FR 62086, 62087 (2004); *see also,* RAM, Inc. d/b/a American Wholesale Distribution Corp., 70 FR 11693, 11694 (2005). Similarly, Mini-Thins has been identified by DEA as a ''prime product'' in this gray market industry. *See, e.g.*, Prachi Enterprises, Inc., 69 FR 69407, 69408 (2004).

As addressed in previous final orders, DEA 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. See, e.g., RAM, Inc. d/b/a American Wholesale Distribution Corp., supra, 70 FR 11693; Volusia Wholesale, 69 FR 69409 (2004).

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 factor 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, a personal residence. See, e.g., John E. McRae d/b/a J & H Wholesale, 69 FR 51480 (2004). Mr. Devangkumar then proposed storing listed chemical products in a rental unit at a storage facility; which investigators reported as also having little to no security. Accordingly, this factor weights against granting Respondent's 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. Devangkumar'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 in particular. 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 have been identified as constituting the gray market for list I chemical products. It is apparent that Jay Enterprises 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, 69 FR 11,652 (2004); Xtreme Enterprises, Inc., supra, 67 FR 76195; K.V.M. Enterprises, 67 FR 70968 (2002); Sinbad Distributing, 67 FR 10232 (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 gray 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. Devangkumar's lack of a criminal record and any 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. Because Respondent's customers have also requested it provide them specific products identified as the preferred precursors for illicit manufacturing, the heightened risk of diversion should Respondent's application be granted is both obvious and unacceptable.

The reasoning of Xtreme Enterprises has been consistently applied by the Deputy Administrator in a series of final orders denying applications for registration. See, TNT Distributors, Inc., 70 FR 12729 (2005); Titan Wholesale, Inc., supra, 70 FR 12,727; RAM, Inc. d/b/a American Wholesale Distribution Corp., supra, 70 FR 11693; Al-Alousi, Inc., 70 FR 3561 (2005); Volusia Wholesale, supra, 69 FR 69409; Prachi Enterprises, Inc., supra, 69 FR 69407; CWK Enterprises, Inc., 69 FR 69400 (2004); J & S Distributors, 69 FR 62089 (2004); Express Wholesale, supra, 69 FR 62086; Absolute Distributing, Inc., 69 FR 62078 (2004).

Finally, due to the apparent lack of safety associated with the use of phenylpropanolamine, factor five is also relevant to Respondent's proposal to distribute that product. DEA has previously determined such a request constitutes a ground under factor five for denial of an application for registration. See J & S Distributors, supra, 69 FR 62089; Gazaly Trading, supra, 69 FR 22561; William E. ''Bill'' Smith d/b/a B & B Wholesale, 69 FR 22559 (2004); Shani Distributors, supra, 68 FR 62324.

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 Jay Enterprises of Spartanburg, Inc., be, and it hereby is denied. This order is effective June 9, 2005.

Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–9252 Filed 5–9–05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Stephen K. Jones, M.D.; Denial of Registration

On November 10, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Stephen K. Jones, M.D. (Dr. Jones) who was notified of an opportunity to show cause as to why DEA should not deny his application for DEA Certificate Registration as a practitioner to handle controlled substances, pursuant to 21 U.S.C. 823 and 824.

The Order to Show Cause alleged in relevant part, that Dr. Jones was not licensed to practice medicine or handle controlled substances in Utah, the state in which he was applying for registration and intended to practice. Secondarily, the Order alleged Dr. Jones had previously been disciplined in Iowa, where he currently lives and practices, for personal drug abuse, signing a fraudulent prescription and diverting controlled substances. The Order to Show Cause also notified Dr. Jones that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Dr. Jones Residence at 3525 Mayfield Road, Iowa City, Iowa and to his proposed registered location in Salt Lake City, Utah. According to certified mail receipt records, the Order to Show Cause sent to his residence was received by Dr. Jones on December 10, 2004. DEA has not received a request for hearing or any other reply from Dr. Jones 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 to the applicant's home and address of record, and (2) no request for hearing having been received, concludes that Dr. Jones is deemed to have waived his wearing right. See David W. Linder, 67 FR 12,579 (2002). After considering material from the investigate 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 on July 2, 2004, Dr. Jones applied for DEA registration to handle Schedule II through IV controlled substances. His proposed registered address was at the LDS Hospital, 8th Avenue & C Street, Salt Lake City, Utah 84143. The application indicated Dr. Jones was previously disciplined by the Iowa Board of Medical Examiners which, in April 2004, had suspended his Iowa license to practice medicine for 30 days and placed it in a probationary status upon his completion of a two month residential treatment program for opioid dependency.

According to information in the investigative file, on July 27, 2004, a Diversion Investigator conducting an inquiry into Dr. Jones application was advised by the Utah Department of Commerce, Division of Occupational and Professional Licensing, that he did not hold a Utah Physician and Surgeon License or state Controlled Substance License. Further, there is no evidence before the Deputy Administrator showing that Dr. Jones has since been granted a license to practice medicine or handle controlled substance in that 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 Rory Patrick Doyle, M.D., 69 FR 11,655 (2004); Dominick A. Ricci, M.D., 58 FR 51,104 (1993); Bobby Watts, M.D., 53 FR 11,919 (1988).

Here, it is clear Dr. Jones is not licensed to practice medicine in Utah, his state of applied-for-registration and practice, and he is not authorized to handle controlled substances in that jurisdiction. Therefore, is not entitled to a DEA registration in that state. As a result of the finding that Dr. Jones lacks state authorization to handle controlled substances in his state of applied-for-registration, the Deputy Administrator concludes it is unnecessary to address further whether his application should be denied based upon the public interest grounds asserted in the Order to Show Cause. See Samuel Silas Jackson, D.D.S., 67 FR 67,145 (2002); Nathaniel-Aikens-Afful, M.D., 62 FR 16,871 (1997); Sam F. Moore, D.V.M., 58 FR 14,428 (1993).

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 the application for DEA Certificate of Registration submitted by Stephen K. Jones, M.D., be, and it hereby is, denied. This order is effective June 9, 2005.

Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–9246 Filed 5–9–05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–56]

Michael J. Millette, M.D.; Revocation of Registration

On May 17, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Michael J. Millette, M.D. (Dr. Millette) of Crystal Lake, Illinois and Elizabethtown, Kentucky. Dr. Millette was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificates of Registration, BM2349012 and BM8086236, as a practitioner, and deny any pending applications for renewal or modification of such registrations 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. Millette was further notified that his DEA registrations were 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 alleged in sum, that Dr. Millette was engaged in illegally prescribing controlled substances as part of a scheme in which controlled substances were dispensed by pharmacies, based on Internet prescriptions issued by Dr. Millette and associated physicians, based solely on their review of Internet questionnaires and without personal contact, examination or bona fide physician/patient relationships. Such prescriptions were not issued ''in the usual course of professional treatment'' and violated 21 CFR 1306.04 and 21 U.S.C. 841(a). This action was part of a nationwide enforcement operation by DEA titled Operation Pharmnet, which targeted online suppliers of prescription drugs, including owners, operators, pharmacists and doctors, who have illegally and unethically been marketing controlled substances via the Internet.