

professed willingness to sell his customers whatever products they wanted and his apparent lack of candor with investigators, when he failed to reveal that his former company had applied for registration to distribute listed chemicals.

Finally, as recommended by Judge Randall, due to the apparent lack of safety associated with the use of phenylpropanolamine, factor five is also relevant to Elk's proposal to distribute that product. DEA has previously determined that 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, supra*, 69 FR 22559; *Shani Distributors, supra*, 68 FR 62324.

Based on the foregoing, the Deputy Administrator concludes that granting Respondent's 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 28 C.F.R. 0.100(b) and 0.104, hereby orders that the pending application for a DEA Certificate of Registration, previously submitted by Elk International, Inc., d.b.a. Tri-City Wholesale, be, and it hereby is, denied. This order is effective June 9, 2005.

Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05-5]

James Marvin Goodrich, M.D. Revocation of Registration

On October 24, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to James Marvin Goodrich, M.D. (Dr. Goodrich) of Springfield, Illinois, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, BG0644244, as a practitioner, pursuant to 21 U.S.C. 824(a)(3) and (a)(4) 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, in part, that Dr. Goodrich's Illinois state license to handle controlled substances had expired and accordingly, he was not authorized to handle controlled substances in Illinois, the state in which he is registered.

On November 8, 2004, Dr. Goodrich, through counsel, timely requested a hearing in this matter. On November 15, 2004, Administrative Law Judge Gail A. Randall (Judge Randall) issued the Government, as well as Dr. Goodrich, an Order for Prehearing Statements.

In lieu of filing a prehearing statement, the Government filed a Motion for Summary Disposition, asserting that Dr. Goodrich's Illinois controlled substance license had expired without being renewed and he was without authorization to handle controlled substances in that State. As a result, the Government argued that further proceedings in the matter were not required. Attached to the Government's motion was a copy of a Certification of Licensure, issued on November 18, 2004, by the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation. That document showed Dr. Goodrich's Licensed Physician Controlled Substances, License No. 336054605, had expired on July 31, 2002, without being renewed.

On November 30, 2004, Judge Randall issued an Order and Notice providing Dr. Goodrich an opportunity to respond to the Government's motion. On December 21, 2004, counsel for Dr. Goodrich filed a response in which he acknowledged Respondent was without authority to handle controlled substances in Illinois as a result of the failure to renew his state controlled substance license. Counsel further stated they would not object to disposition based on that ground.

December 29, 2004, Judge Randall issued her Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Randall granted the Government's Motion for Summary Disposition, finding Dr. Goodrich lacked authorization to handle controlled substances in Illinois, the jurisdiction in which he is registered. Judge Randall recommended that Dr. Goodrich's DEA registration be revoked on the basis that he lacks state authority to handle controlled substances.

No exceptions were filed by either party to the Opinion and Recommended Decision and on February 2, 2005, the record of these proceedings was transmitted to the Office of the DEA Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Decision of the Administrative Law Judge.

The Deputy Administrator finds that Dr. Goodrich holds DEA Certificate of Registration, BG0644244, as a practitioner. The Deputy Administrator further finds that Dr. Goodrich's Illinois controlled substance license expired on July 31, 2002, and there is no evidence in the record indicating it has been renewed or reinstated. Therefore, the Deputy Administrator finds Dr. Goodrich is currently not licensed to handle controlled substances 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 *Kanwaljit S. Serai, M.D.*, 68 FR 48,943 (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. Goodrich is not currently licensed to handle controlled substances in Illinois, where he is registered with DEA. Therefore, he is not entitled to maintain that registration. Because Dr. Goodrich is not entitled to a DEA registration in Illinois due to lack of state authorization to handle controlled substances, the Deputy Administrator concludes it is unnecessary to address whether Dr. Goodrich's registration should be revoked based upon the remaining public interest grounds asserted in the Order to Show Cause. See *Fereida Walker-Graham, M.D.*, 68 FR 24,761 (2003); *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 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, BG0644244, issued to James Marvin Goodrich, 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 9, 2005.

Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

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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. Devangkumar 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