

medical license has been surrendered. Therefore, the Deputy Administrator finds that Dr. Angeluzzi is currently not authorized to practice medicine in the State of Connecticut. As a result, it is reasonable to infer that he is also without authorization 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 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 that Dr. Angeluzzi's state medical license was surrendered after disciplinary proceedings were initiated against him and there is no information before the Deputy Administrator indicating that his license has been reinstated or a new license issued. As a result, Dr. Angeluzzi is not authorized to practice medicine or handle controlled substances in Connecticut, 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 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, AA2504151, issued to Jay D. Angeluzzi, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of the aforementioned registration be, and hereby are, denied. This order is effective June 9, 2005.

Dated: May 2, 2005.

**Michele M. Leonhart,**  
*Deputy Administrator.*

[FR Doc. 05-9247 Filed 5-9-05; 8:45 am]

BILLING CODE 4410-09M

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 03-25]

#### **ELK International, Inc., d.b.a. Tri-City Wholesale; Denial of Application**

On April 11, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to ELK International,

Inc., d/b/a Tri-City Wholesale (Respondent/Elk) proposing to deny its application for a DEA Certification of Registration as a distributor of list I chemicals. The Order to Show Cause alleged, in sum that granting the application to distribute list I chemicals to what DEA has identified as the "gray market," would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h) and 824(a).

Respondent, proceeding pro se, requested a hearing on the issues raised by the Order to Show Cause and the matter was docketed before Administrative Law Judge Gail A. Randall. Respondent subsequently retained counsel and following pre-hearing procedures, a hearing was held in Memphis, Tennessee, on March 9, 2004. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Subsequently, both parties filed Proposed Findings of Fact, Conclusions of Law, and Argument.

On October 7, 2004, Judge Randall issued her Recommended Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Opinion and Recommended Ruling), recommending that Respondent's application to distribute pseudoephedrine and ephedrine chemical products be granted, subject to "close monitoring" by DEA. She did recommend denying ELK registration to distribute phenylpropanolamine. The Government filed exceptions to the Opinion and Recommended Ruling and on November 16, 2004, Judge Randall transmitted the record of these proceedings to the 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 hereinafter set forth. Except as otherwise set forth in this final order, the Deputy Administrator adopts the findings of fact and conclusions of law of the Administrative Law Judge. The Deputy Administrator agrees with recommendation that Respondent be denied registration to distribute phenylpropanolamine. However, she disagrees with the recommendation that Respondent be approved to distribute ephedrine and pseudoephedrine, even under monitored conditions.

On May 9, 2002, Respondent, a Tennessee corporation owned by Mr. and Mrs. Nafez Elkhayyat, located in Memphis, submitted its application for registration as a distributor of list I chemicals, seeking approval to

distribute pseudoephedrine, ephedrine and phenylpropanolamine.

Prior to moving to Memphis, the Elkhayyats had owned Tri-State Wholesale, Elk International, Inc. (Tri-State), located in East Ridge, Tennessee, a suburb of Chattanooga. In May 2001, Tri-State applied for DEA registration to distribute list I chemicals in an application signed by Mrs. Elkhayyat. During a pre-registration inspection by a Diversion Investigator from DEA's Nashville Office, Mr. Elkhayyat was interviewed and stated he intended to carry whatever products his customers wanted.

Despite having operating a retail grocery store for 27 years, Mr. Elkhayyat had little or no knowledge of listed chemicals, was unaware that they were used in illicit methamphetamine manufacturing and could not identify the names of products containing listed chemicals.

While Tri-State was not registered with DEA, the Diversion Investigator found numerous name-brand products at its facility containing listed chemicals. These included Dayquil, Nyquil, Advil Cold and Sinus, Tylenol Cold and Sinus, Anacin Cough and Cold, Alka Seltzer Plus and Robitussin. Mr. Elkhayyat advised he had purchased these items from a grocery store in Texas and readily agreed to box them up and return them to the supplier, which he did while the Diversion Investigator was still on the premises. He was also provided materials and a briefing regarding the dangers of diversion and the record keeping/reporting requirements for registrants.

An Order to Show Cause proposing to deny Tri-State's application was issued by DEA on May 21, 2002, and sent to the company's address in East Ridge. However, by then the Elkhayyats had moved to Memphis and sold Tri-State's assets to H & R Corporation, d.b.a. Tri-State Wholesale (H & R). At the time, H & R was not seeking to distribute listed chemicals and the Elkhayyats had not retained any ownership or control over H & R. Accordingly, DEA's Office of Chief Counsel directed that Tri-State's application be administratively withdrawn, as the entity submitting it no longer existed.<sup>1</sup>

In June 2002, a different Diversion Investigator than the one who interviewed Mr. Elkhayyat in East Ridge a year earlier, conducted the pre-

<sup>1</sup> It is noted that H & R Corporation's owners subsequently applied for DEA registration to distribute list I chemicals. An Order to Show Cause proposing to deny H & R registration was issued and the matter is currently pending final agency action.

registration investigation on Elk's application. He met Mr. Elkhayyat and his brother at the company's Memphis facility and they discussed the problem of diversion and record keeping requirements. Despite the information having been provided him during the first pre-registration investigation, Mr. Elkhayyat did not indicate that he had any familiarity with reporting requirements. He also failed to disclose that his former company had previously applied for a DEA registration.

In general, the Diversion Investigator was satisfied with Elk's physical security and intended policies for verifying the legitimacy of prospective customers. While the Elkhayyats did not yet have a customer list, they indicated they intended to sell listed chemicals on a wholesale basis, primarily to "convenience stores, service stations, gasoline stations, [and] small grocery stores."

After returning to his office, the Diversion Investigator learned the Elkhayyats had applied for registration under the Tri-State name and he prepared a recommendation that an Order to Show Cause be issued to Elk based primarily on its intent to distribute list I chemicals to what DEA has termed the "grey market."

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 the symptoms resulting 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 issued a public health advisory request drug companies to discontinue marketing products containing phenylpropanolamine, due to risk of hemorrhagic stroke. As a result, many pharmaceutical companies have stopped using phenylpropanolamine as an active ingredient. *See, Gazaly Trading*, 69 FR 22561 (2004).

As testified to by government witnesses and as addressed 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 8,682 (2004); *Denver Wholesale*, 67 FR 99986 (2002); *Yemen Wholesale Tobacco and Candy Supply, Inc.*, 67 FR 9997 (2002).

A Diversion Control Group Supervisor and Special Agent testified at the hearing regarding the rapid proliferation of clandestine methamphetamine laboratories in Tennessee and its adjoining states and described the local methods of production. They recounted the multiple health hazards and social costs stemming from the production and abuse of methamphetamine and testified to a dramatic increase in local clandestine laboratories. As discussed in several recently published final orders, Tennessee now leads the DEA Atlanta Region in the number of clandestine laboratories seized. *See, e.g., Prachi Enterprise, Inc.*, 69 FR 69407 (2004); *CWK Enterprises, Inc.*, 69 FR 69400 (2004). Further, DEA has found that local "[d]istributors or retailers serving the illicit methamphetamine trade observe no borders and trade across state lines." *Id.*, 69 FR at 69401.

The Special Agent credibly testified that local manufacturers typically acquired their pseudoephedrine and ephedrine precursors from area convenience stores and small "mom and pop" stores and would patronize multiple stores, in order to deflect attention from their buying patterns. In his experience, the precursor most often found in area laboratories was Max Brand, followed by other "off name" brands, such as Mini-Thins, Pseudo-60's and Two-Ways. The preferred pseudoephedrine strength of illicit manufacturers is 60 mg. The Special Agent further testified that he had never personally encountered nationally known brand names at illicit sites, such as Advil Cold and Sinus, Tylenol Allergy and Sinus, Tylenol Sinus, Tylenol Cold, Nyquil, Dayquil, Theraflu, BC Allergy Sinus Cold or Alka Seltzer.

By written declaration, a DEA Diversion Investigator contrasted the "traditional" market for list I chemicals with what DEA has termed the "gray market" for these products. The traditional market, characterized by a short distribution chain from manufacturer to distributor to retailer, typically includes large chain grocery stores, chain pharmacies, large convenience stores and large discount stores. The gray market is characterized by additional layers of distribution and includes such non-traditional retailers

as small convenience stores, gas stations and other retail establishments where customers do not usually purchase over-the-counter medications. These non-traditional retailers typically sell higher-strength products in larger package sizes, such as 100 or 120 count bottles of 60 mg. pseudoephedrine. The Diversion Investigator also identified the off-name brands found in disproportionate numbers during clandestine laboratory seizures. These included Max Brand, Mini Two Way, MiniThin and Action-Pseudo products.

Max Brand Pseudo 60s has previously been identified by DEA as the "precursor product predominantly encountered and seized at clandestine methamphetamine laboratories" and convenience stores are the "primary source" for the purchase of "Max Brand products, which are the preferred brand for use by illicit methamphetamine producers \* \* \*". *See, Express Wholesale*, 69 FR 62086, 62087 (2004); *see also, RAM, Inc. d/b/a American Wholesale Distribution Corp.*, 70 FR 11693 (2005).

A Group Supervisor from DEA's Nashville office testified that, in his view, the area's demand for pseudoephedrine and ephedrine for legitimate medical purposes, did not justify the supply.

Mr. Elkhayyat testified at the hearing that he and his wife were Elk's sole shareholders and the company sold candy, tobacco and other sundry items on a wholesale basis to area convenience stores, service stations and small restaurants. Judge Randall found Mr. Elkhayyat credibly testified that, prior to Tri-State's application, he had been a retail grocer and was unaware that a license was needed to distribute ephedrine and pseudoephedrine products on a wholesale basis.

After selling Tri-State to H & R in 2001, the Elkhayyats moved to Memphis and began their wholesale distribution business under Elk International's corporate charter. Mr. Elkhayyat testified that he had no interest in selling "Max Brand or Mini Thins" and would abide by DEA regulations. He testified the company would sell only name brand products such as Advil Cold and Sinus, Tylenol Cold and Sinus, Nyquil, Dayquil, Theraflu, Alka Seltzer, Benadryl and Vick's Cough Medicine, which the Special Agent had testified were rarely, if ever, found at clandestine laboratories.

By declaration, the Government introduced evidence regarding ephedrine and pseudoephedrine sales and the convenience store market from Mr. Jonathan Robbin, a consultant in marketing information systems and

databases, who is an expert in statistical analysis and quantitative marketing research.

Using the 1997 United States Economic Census of Retail Trade, Mr. Robbin tabulated data indicating that over 97% of all sales of non-prescription drug products, including non-prescription cough, cold and nasal congestion remedies, occur in drug stores and pharmacies, supermarkets, large discount merchandisers, mail-order houses and through electronic shopping. He characterized these five retail industries as the traditional marketplace where such goods are purchased by ordinary customers.

Analyzing national sales data specific to over-the-counter, non-prescription drugs containing pseudoephedrine, Mr. Robbin's research and analysis showed that a very small percentage of the sales of such goods occur in convenience stores; only about 2.6% of the Health and Beauty Care category of merchandise or 0.05% of total in-store (non-gasoline) sales. He determined that the normal expected retail sales of pseudoephedrine tablets in a convenience store would range between \$10.00 and \$30.00 per month, with an average monthly sales figure of about \$20.00 and that sales of more than \$100.00 in a month would be expected to occur in a random sampling about once in one million to the tenth power.

According to Mr. Robbin, "[h]alf of the Tennessee stores analyzed showed implied sales over ten times expectation, with ten of them over twenty times expectation." These differences were extremely significant statistically and in his expert opinion, small Tennessee convenience stores were not selling pseudoephedrine and ephedrine products "for their intended purpose as non-prescription drugs" and the assumption that they were supplying the gray market was statistically supported "many times over\* \* \*"

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, as determined under that section. Section 823(h) requires 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 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 considered in the disjunctive, the Deputy Administrator may rely on any one or 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.,* Direct Wholesale, 69 FR 11654 (2004); Energy Outlet, 64 FR 14269 (1999); Henry J. Schwartz, Jr., M.D., 54 FR 16422 (1989).

As to factor one, maintenance by the applicant of effective controls against diversion, the Deputy Administrator agrees with Judge Randall that Elk's proposed physical security is adequate. With regard to Elk's proposed monitoring and business practices, Judge Randall noted the company's proposed practices "seemed adequate" and that, while the company had yet to prove the viability of these practices, she concluded "such a lack would support close scrutiny by DEA, but not\* \* \* outright denial." Judge Randall therefore concluded that factor one weighed in favor of registration.

The Deputy Administrator disagrees with that condition. As noted by the Government in its Objections, even if Respondent was able to monitor sales to gray market customers for excessive amounts, DEA has previously found that gray market retailers supplying chemicals for illicit use regularly acquire their product from multiple distributors in order to mask their acquisition of large amounts of listed chemicals. *See, Titan Wholesale, Inc., 70 FR 12,727-92005*. Thus, so long as Elk was distributing wholesale to this suspect market, even sincere efforts by Respondent to self-regulate its customers would not thwart gray market retailers from obtaining precursor chemicals from other distributors, as well as from Elk, and then reselling them for illicit purposes.

Further, a policy of DEA Headquarters directing field offices to provide individual registrants extraordinary scrutiny and monitoring, simply to justify an otherwise unwarranted registration, would ultimately have an adverse cumulative impact on the execution of DEA's mission, given the limited assets and extraordinary

demands placed upon its personnel in the field.

In sum, the Deputy Administrator concludes that factor one weighs against granting Respondent's application, primarily because of its intent to participate in the gray market. *See, Titan Wholesale, Inc., supra, 70 FR 12727; TNT Distributors, Inc., 70 FR 12729 (2005)*.

With regard to factor two, Respondent's compliance with applicable Federal, state and local law, Judge Randall concluded this factor weighs in favor of registration. In doing so, she rejected the Government's argument that Respondent's owners, while doing business as Tri-State, had distributed brand name listed chemical products without a registration, thus violating law and regulations. Because the products were only found by the Diversion Investigator stocked on Tri-State's shelves and no direct evidence was introduced showing they had been resold, Judge Randall concluded there was insufficient evidence to show the Elkhayyat's had, in fact, distributed the listed chemicals products, thus triggering a registration requirement.

The Government objected to that conclusion, arguing Tri-State was actively in business as a wholesale at the time of the pre-registration inspection and that all of the products at its unregistered facility, including listed chemicals, were there for distribution to retail customers, not merely for storage. The Deputy Administrator agrees with the Government that, under the facts of this case, it is appropriate to infer the Elkhayyats, while operating Tri-State, distributed, attempted to distribute or possessed with the intent to distribute, list I chemicals without a requisite registration. However, the Deputy Administrator considers this apparent non-compliance mitigated by Mr. Elkhayyat's then-lack of knowledge as to what products actually contained listed chemicals and his cooperation in immediately returning the items to his out of state supplier.

More significant for factor two and factor five as well, the Deputy Administrator notes that state legislatures throughout the United States are actively considering legislation designed to impede the ready availability of precursor chemicals. Many of these proposals are similar to legislation enacted by the State of Oklahoma, titled the "Oklahoma Methamphetamine Reduction Act of 2004." Under that measure, as of April 6, 2004, pseudoephedrine tablets were designated as Schedule V controlled

substances and may be sold only from licensed pharmacies within that state.

As a result, it is prohibited in Oklahoma to sell these products from gray market establishments, such as independent convenience stores, which have contributed so much to the scourge of methamphetamine abuse. See, e.g., Express Wholesale, *supra*, 69 FR at 62809 [denying DEA registration to an Oklahoma gray market distributor, in part, because of new state restrictions].

A review of data for 2004 reveals the Oklahoma law has resulted in an apparent reduction in the number of seizures involving clandestine methamphetamine laboratories in the state. These developments are encouraging and represent an important step in the ongoing battle to curb methamphetamine abuse in the United States. State legislation, such as Oklahoma's, reflects a positive trend and growing recognition that the diversion of precursor chemicals through the gray market insidiously impacts public health and safety. See, e.g., Tysa Management, d/b/a Osmani Lucky Wholesale, 70 FR 12732, 12734 (2005) [denying registration to intended Oklahoma distributor, in part, on basis of enactment of recent state legislation]; Express Wholesale, *supra*, 69 FR at 62089.

Of particular consequence to Elk and similarly situated Tennessee applicants and registrants, after Judge Randall signed her Opinion and Recommended Ruling, legislation was enacted by the State of Tennessee that is patterned after the Oklahoma initiative. That legislation (Senate Bill 2318/House Bill 2334), collectively known as the "Meth-Free Tennessee Act of 2005," was signed into law by Governor Phil Bredeson on March 31, 2005, and makes it unlawful for establishments, other than licensed pharmacies, to sell tableted pseudoephedrine products in Tennessee after April 1, 2005. This includes both name brand and off-name brand products.

Accordingly, Respondent's entire intended customer base is now prohibited by state law from selling the pseudoephedrine products Elk seeks DEA registration to distribute. Thus, factor two weighs heavily against registration. See, Tysa Management, d/b/a Osmani Lucky Wholesale, *supra*, 70 FR at 12734; Express Wholesale, *supra*, 69 FR at 62089.

As to factor three, any prior conviction record relating to listed chemicals or controlled substances, the Deputy Administrator concurs with Judge Randall that there is no evidence or any prior convictions of Respondent

or its owners related to listed chemicals or controlled substances. Accordingly, this factor weighs in favor of registration.

With regard to factor four, the applicant's past experience in distributing listed chemicals, Judge Randall found that while Elk's owners had no prior experience in manufacturing or distributing these products, Mr. Elkhyyat had extensive retail grocery experience and had taken steps to improve his knowledge in this area. However, recognizing that lack of experience in handling list I chemicals has been a factor in prior DEA final orders denying registration, Judge Randall found this factor weighted against registration in a "close call." The Deputy Administrator agrees. See, e.g., Direct Wholesale, *supra*, 69 FR 11654; ANM Wholesale, 69 FR 116522 (2004); Xtreme Enterprises, Inc., 67 FR 76195 (2002).

With regard to factor five, other factors relevant to public health and safety, Judge Randall acknowledged DEA precedent denying registration to grey market distributors under that factor, in particular, Xtreme Enterprises, Inc., *supra*, 67 FR 76195. In that case there was no evidence the applicant's owner had failed to comply with Federal, State or local law or had any prior convictions relating to controlled substance or chemicals. Further, she was willing to provide adequate security for the listed chemicals.

However, the Deputy Administrator found Xtreme's owner had only a rudimentary knowledge of what would constitute a suspicious order and no experience in the manufacture or distribution of listed chemicals. Most significant for this and similar cases, the Deputy Administrator also found that "[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 76197.

However, in her Opinion and Recommended Ruling, Judge Randall distinguished the facts of Xtreme Enterprises from this matter. In Xtreme, the respondent's supplier had received two warning letters from DEA that its product had been found in situations indicating their use in illicit methamphetamine manufacturing. Additionally, the applicant had received requests for list I chemicals in packaging forms that were not normally seen in traditional retail establishments.

In contrast, Judge Randall found Respondent in this case only intended to distribute name brand products and did not intend to distribute Max Brand, the precursor product most favored by illicit manufacturers. Based on these distinctions, Judge Randall concluded Elk's intent to distribute listed chemicals to the gray market did not "weigh as heavily" under factor five as it did against Xtreme Enterprises.

DEA has expansively applied the analysis of Xtreme Enterprises to a multitude of applicants seeking to do business in the gray market. See e.g., Express Wholesale, *supra*, 69 FR 624086; Value Wholesale, 69 FR 58548 (2004); K & Z Enterprises, Inc., 69 FR 5175 (2004); William E. "Bill" Smith d/b/a B & B Wholesale, 69 FR 2259 (2004); Branex Incorporated, *supra*, 69 FR 8682; Shop It for Profit, 69 FR 1311 (2003); Shani Distributors, 68 FR 62324 (2003).

As in those cases, the Elkhayyats' lack of criminal records, previous general compliance with the law and regulations and their professed willingness to comply with regulations and guard against diversion, are far outweighed by their intent to sell ephedrine and pseudoephedrine, almost exclusively, in the gray market.

This reasoning has also been consistently applied by the Deputy Administrator in a series of final orders published after Judge Randall issued her Opinion and Recommended Ruling in this matter. See, TNT Distributors, Inc., *supra*, 70 FR 12729; Titan Wholesale, Inc., *supra*, 70 FR 1227; 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).

In any event, Judge Randall's reason for not giving Xtreme Enterprises more weight in this matter, i.e., Respondent's intent to carry only brand name products, has been mooted by Tennessee's new requirement that all pill and tablet pseudoephedrine products, including those marketed under traditional brand names, be sold only through registered pharmacies. As this statute, addressed more fully under factor two, effectively bars distribution of these products through Tennessee's gray market establishments, it is also relevant under factor five and weighs heavily against Respondent's registration.

The Deputy Administrator also notes with concern Mr. Elkhayyat's initially

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.*

[FR Doc. 05-9251 Filed 5-9-05; 8:45 am]

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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.