The last notification was filed with the Department on February 14, 2005. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on March 14, 2005 (70 FR 12501).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

John Vanags Denial of Application

On October 8, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to John Vanags (Respondent), d/b/a Distribution General. The Show Cause Order proposed to deny Respondent's application for a DEA Certificate of Registration as a distributor of List I chemicals on the grounds that Respondent's registration would be inconsistent with the public interest. See 21 U.S.C. 823(h).

The Show Cause Order specifically alleged that Respondent was proposing to sell List I chemical products containing ephedrine, pseudoephedrine, and phenylpropanolamine to gas stations and convenience stores in the Chicago, Illinois area, and that these retail outlets constitute the non-traditional or ''gray market'' for these products. See Show Cause Order at 2. The Show Cause Order further alleged that many of these retailers ''purchase inordinate amounts of these products and become conduits for the diversion of listed chemicals into illicit drug manufacturing.'' Id. The Show Cause Order also alleged that Respondent admitted that he had no prior experience in the distribution of List I chemicals, see id., that Respondent was ''unfamiliar with his customers,'' id. at 4, and that Respondent has ''little familiarity with his potential suppliers.'' Id. Finally, the Show Cause Order alleged that granting Respondent's application for registration ''would likely lead to increased diversion of List I chemicals.'' *Id.*

On October 8, 2004, DEA attempted to serve the Show Cause Order by certified mail to Respondent's business address as given in his application. The Order was, however, returned unclaimed. Thereafter, on March 24, 2005, a DEA Diversion Investigator (DI) personally served Respondent with the Show Cause Order.

Since the effectuation of service, neither Respondent, nor anyone purporting to represent him, has responded. Because (1) more than thirty days have passed since Respondent received the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived his right to a hearing. See 21 CFR 1309.53(c). I therefore enter this final order without a hearing based on relevant material in the investigative file and make the following findings.

Findings

Ephedrine and pseudoephedrine are List I chemicals that, while having therapeutic uses, are easily extracted from lawful products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. See 21 U.S.C. § 802(34); 21 CFR 1308.12(d). Phenylpropanolamine (PPA) is also a List I chemical, which can be used to manufacture methamphetamine. In November 2000, the FDA issued a public health advisory regarding PPA based on a study that found that use of PPA increases the risk of hemorrhagic stroke.[1]

Methamphetamine is an extremely potent central nervous system stimulant. A–1 Distribution Wholesale, 70 FR 28573 (2005). Methamphetamine abuse has destroyed lives and families, ravaged communities, and created serious environmental harms.

Respondent is the owner of Distribution General, a sole proprietorship. The firm sells novelty items, sunglasses, lighters and collectibles to gas stations and convenience stores in the Chicago area.

On April 3, 2002, Respondent applied for a DEA Certificate of Registration as a distributor of the List I chemicals ephedrine, pseudoephedrine, and PPA. On May 23, 2002, two Diversion Investigators (DIs) visited Respondent at the address of his proposed registered location, which at the time was a high crime area located in Maywood, Illinois.[2] While the proposed location had a dead bolt lock, a pad lock, a magnetic contact switch on the back door, and bars on the windows, the building had been burglarized numerous times.[3]

Respondent told the DIs that he had handled over-the-counter medicine while serving in the U.S. Army Medical Corps, but that he had no experience in the distribution of List 1 chemicals. Respondent informed the DIs that he intended to sell List I chemical products to convenience stores and gas stations in the Chicago area.

Respondent told the DIs that he had four suppliers: Biotek Pharmaceuticals, McNeil Consumer & Specialty Pharmaceuticals, Bayer Consumer Care Division, and Novartis Consumer Health, Inc. He also told the DIs that he intended to sell Alka Seltzer Plus Cold & Sinus, Theraflu, Efedrin and Tylenol PM.

The DIs subsequently found various discrepancies in the information Respondent provided about his suppliers. For example, Respondent provided a phone number for McNeil, but the number was for the company's consumer hotline and not for its distribution center. Respondent provided an address for Bayer, but Bayer did not have a DEA registration at the address. Finally, the DIs noted that Respondent had only provided a phone number for Novartis and no address. The DIs thus concluded that Respondent lacked essential knowledge about his suppliers.

The DIs also conducted verification visits at three entities that Respondent claimed to have done business with. The person working at the first entity—a convenience store—had not done business with Respondent's firm. The second entity was no longer in business. Finally, persons working at the third entity—a gas station—were not familiar with Respondent's firm.

Subsequently, and without notifying DEA of this development for months, Respondent moved his business to a warehouse in a low crime area in Steger, Illinois. Respondent told the DIs that he did not have a complete security system but that he intended to add cameras, motion detectors and a surveillance system, which would allow him to monitor the warehouse from home. Respondent, however, has not submitted documentation that he ever upgraded his security system.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless I determine that

[1] More recently, on December 22, 2005, the FDA issued a notice of proposed rulemaking, which proposed to reclassify over-the-counter PPA products as ''not generally recognized as safe and effective.'' U.S. FDA, Center for Drug Evaluation and Research, Phenylpropanolamine (PPA) Information Page *http.//www.fda.gov/cder/drug/infopage/ppa/* (visited June 15, 2006).

[2] At the time of the pre-registration investigation, Respondent's business was located at 17 North 5th Ave., Maywood, Illinois. At some point thereafter, Respondent moved his business to 3129 Louis Sherman Drive, Steger, Illinois. Respondent, however, did not notify DEA of this fact until March 2005.

[3] The DIs also conducted a criminal background check on Respondent; the check revealed no adverse information.

the registration would be inconsistent with the public interest. In making that determination, Congress directed that I consider the following factors:

(1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) Compliance by the applicant with applicable Federal, State, and local law;

(3) Any prior conviction record of the applicant 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.

Id.

''[T]hese factors are considered in the disjunctive.'' Joy's Ideas, 70 FR 33195, 33197 (2005). I may rely on any one or combination of factors, and may give each factor the weight I deem appropriate in determining whether a registration should be revoked or an application for a registration be denied. See *id.* See also Energy Outlet, 64 FR 14269 (1999). Having considered all of the factors in this case, I conclude that Respondent's application should be denied.

Factor One—Maintenance of Effective Controls Against Diversion

The investigative file does not address whether Respondent will comply with DEA requirements pertaining to recordkeeping and reports. Furthermore, Respondent's initial proposed location presented a major security concern.

Respondent, however, submitted a letter changing his business address before he received the Show Cause Order. Under DEA's regulations, ''[a]n application may be amended * * * without permission of the Administration at any time before the date on which the applicant receives an order to show cause.'' 21 CFR 1309.36.

I acknowledge that Respondent's new location may well have provided adequate security had Respondent installed the alarm system he discussed with the DIs. I also acknowledge that the Government attempted to serve the Show Cause Order in October 2004, and the only reason the order was not received was because Respondent failed to notify DEA that he had changed his business address. Ultimately, I need not decide the issue of whether Respondent maintains effective controls against diversion because under agency precedent, there are numerous other grounds to deny the application.

Factors Two and Three—Compliance With Applicable Law and the Applicant's Prior Record of Relevant Criminal Convictions

The investigative file contains no evidence that Respondent would not comply with applicable Federal, State, or local laws. Moreover, the investigative file indicates that Respondent has never been convicted of a criminal offense involving controlled substances or chemicals under Federal or State law. Both factors thus weigh in favor of granting Respondent's application.

Factor Four—Past Experience in the Manufacture or Distribution of Controlled Substances

Respondent acknowledged that he has no prior experience in the manufacture or distribution of List I chemicals. Because of the potential for diversion, DEA precedent establishes that an applicant's lack of experience in distributing List I chemicals is a highly important consideration that weighs heavily against granting an application for registration. See Jay Enterprises, 70 FR 24620, 24621 (2005); ANM Wholesale, 69 FR 11652, 11653 (2004); Extreme Enterprises, 67 FR 76195, 76197 (2002). Respondent's lack of experience thus weighs against granting the application.

Factor Five—Other Factors That Are Relevant To and Consistent With Public Health and Safety

Numerous DEA cases recognize that the sale of certain List I chemical products by non-traditional or gray market retailers is an area of particular concern in preventing diversion of these products into the illicit manufacture of methamphetamine. See, e.g., Joey Enterprises, 70 FR 76866, 76867 (2005). As Joey Enterprises explains, ''[w]hile there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to [gas stations and convenience stores], DEA has nevertheless found that [these entities] constitute sources for the diversion of listed chemical products.'' Id. See also TNT Distributors, 70 FR 12729, 12730 (2005) (special agent testified that ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores''); OTC Distribution Co., 68 FR 70538, 70541 (2003) (noting ''over 20 different seizure of [gray market distributor's] pseudoephedrine product at clandestine sites,'' and that in eight month period distributor's product ''was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone''); MDI Pharmaceuticals, 68 FR 4233, 4236 (2003) (finding that ''pseudoephedrine products distributed by [gray market supplier] have been uncovered at numerous clandestine methamphetamine settings throughout the United States and/or discovered in the possession of individuals apparently involved in the illicit manufacture of methamphetamine'').

Numerous DEA final orders recognize that there is a substantial risk of diversion of List I chemicals into the illicit manufacture of methamphetamine when these products are sold by non-traditional retailers. See, e.g., Joy's Ideas, 70 FR at 33199 (finding that the risk of diversion was ''real, substantial and compelling''); Jay Enterprises, 70 FR at 24621 (noting ''heightened risk of diversion'' should application be granted); Y & M Distributions, Inc., 67 FR 10234, 10235 (2002) (noting ''unacceptable risk of diversion'' in denying application). Under these and other cases, an applicant's proposal to sell List I chemicals into the non-traditional market weighs against the granting of a registration. So too here.

There are other factors that support a finding that granting Respondent's application would be inconsistent with public health and safety. While Respondent represented that he intended to sell both traditional-market and gray-market products, the information he provided regarding both his potential suppliers and customers raises substantial concerns. The information with respect to several suppliers was incomplete. In addition, in DEA's experience, larger drug and consumer product companies typically distribute their goods through wholesalers; it would be unusual for these companies to deal directly with an entity such as Respondent's. At a minimum, the information Respondent provided regarding his suppliers suggests a lack of knowledge of the business.

Moreover, Respondent's potential customers had either not done business with him, were not familiar with his firm, or were out of business. This information raises a substantial concern as to whether Respondent had any legitimate customers. Cf. Prachi Enterprises, Inc., 69 FR 69407, 69408 (2004).

Finally, I note that Respondent applied to distribute PPA. Most significantly, he did so more than a year after the FDA issued a public health advisory and asked drug companies to stop marketing products containing the

chemical. DEA has previously held that ''an applicant's request to distribute [PPA] constitutes a ground under factor five for denial'' of an application. ANM Wholesale, 69 FR 11652, 11653 (2004); see also Shani Distributors, 68 FR 62324 (2003). In light of the FDA's advisory, Respondent's proposal to sell PPA raises a serious concern that the purchasers of these products would ultimately use them to manufacture methamphetamine.

Having considered all of the statutory factors, I conclude that granting the application would be inconsistent with the public interest. In particular, I find that Respondent's proposal to sell into the non-traditional market, his lack of experience in distributing List I chemicals, his evident lack of business knowledge, his provision of inadequate information regarding potential customers, and his proposal to sell PPA, greatly outweigh Respondent's lack of a criminal record and the finding that there is no evidence of non-compliance with applicable laws.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) and 0.104, I hereby order that the previously submitted application of John Vanags, d/b/a Distribution General, for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is, denied. This order is effective August 11, 2006.

Dated: July 5, 2006.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

David M. Starr Denial of Application

On February 4, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to David M. Starr (Respondent), d/b/a Northern Starr Products. The Show Cause Order proposed to deny Respondent's application for a DEA Certificate of Registration as a distributor of List I chemicals on the ground that Respondent's registration would be inconsistent with the public interest. See 21 U.S.C. 823(h).

The Show Cause Order specifically alleged that Respondent was proposing to sell ephedrine and pseudoephedrine products to gas stations and convenience stores in the Milwaukee, Wisconsin area, and that these retail outlets constitute the ''gray market'' for these products. The Show Cause Order alleged that there is a ''high incidence of diversion'' of ephedrine and pseudoephedrine products from this market into the illicit manufacture of methamphetamine and that methamphetamine availability ''has been on the increase in the Western district of Wisconsin.'' See Show Cause Order at 2. Finally, the Show Cause Order alleged that Respondent had no experience in distributing List I chemicals and that granting Respondent's registration ''would likely lead to increased diversion of List I chemicals.'' Id. at 4.

The Show Cause Order was served by certified mail, return receipt requested, and on February 16, 2005, Respondent acknowledged receipt. Since that time, neither Respondent, nor anyone purporting to represent him, has responded. Because (1) more than thirty days have passed since Respondent's receipt of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived his right to a hearing. See 21 CFR 1309.53(c). I therefore enter this final order without a hearing based on relevant material in the investigative file and make the following findings.

Findings

Ephedrine and pseudoephedrine are List I chemicals that, while having therapeutic uses, are easily extracted from lawful products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. See 21 U.S.C. 802(34); 21 CFR 1308.12(d). As noted in numerous prior DEA orders, ''methamphetamine is an extremely potent central nervous system stimulant.'' A–1 Distribution Wholesale, 70 FR 28573 (2005). Methamphetamine abuse has destroyed lives and families, ravaged communities, and created serious environmental harms.

Respondent is the sole owner and operator of Northern Starr Products. Northern Starr distributes a variety of novelty items to gas stations and a few conveniences stores in the Milwaukee area. The business is located at Respondent's residence in West Bend, Wisconsin.

On May 30, 2002, Respondent submitted to DEA an application for a registration as a distributor of the List I chemicals ephedrine and pseudoephedrine. On November 7, 2002, two DEA Diversions Investigators (DIs) met with Respondent to conduct a pre-registration investigation. Respondent proposed to sell eleven different List I chemical products including two tablets packs of such over-the-counter products as Advil Cold and Sinus, Tylenol Allergy/Sinus, Nyquil & Dayquil. Respondent, however, also proposed to sell several products containing 25 mg of ephedrine in 60-count bottle sizes.

Respondent informed the DIs that he had no previous experience handling List I chemical products. Respondent further advised the DIs that the business was run out of the basement of his home and that he is the sole employee. The home is located in a residential development, which is surrounded by farmland and prairie land.

Respondent told the DIs that he would store List I chemical products in a closed-off area of the basement. According to the investigative file, the home has door knob locks on the front and back doors. The investigative file contains no indication that Respondent's home has an alarm system.

Respondent also discussed with the DIs the record keeping requirements for List I chemicals; Respondent appeared to understand them. Respondent also provided the DIs with the name and address of his supplier, as well as the names and addresses of the customers who he expected would purchase List I chemical products. Respondent's proposed supplier has a valid DEA registration. Moreover, the investigative file contains no adverse information with respect to any of Respondent's proposed customers. Finally, the investigative file contains no adverse information with respect to Respondent's compliance with applicable laws or criminal history.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless I determine that the registration would be inconsistent with the public interest. In making that determination, Congress directed that I consider the following factors:

(1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) Compliance by the applicant with applicable Federal, State, and local law;

(3) Any prior conviction record of the applicant 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