another product (Lipodrene), which also contained ephedrine alkaloids. On January 12, 2006, the U.S. Attorney's Office filed an additional complaint which sought the forfeiture of these products. U.S. Marshalls seized these products, which were valued at approximately $ 16,000.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless the registration would be ''inconsistent with the public interest.'' In making this 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.

''These factors are considered in the disjunctive.'' *Joy's Ideas*, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether an application for registration should be denied. *See, e.g., David M. Starr*, 71 FR 39367 (2006); *Energy Outlet*, 64 FR 14269 (1999). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Here, I conclude that an analysis of each factor is unnecessary and that Respondent's application should be denied based on Factor Two, its record of non-compliance with applicable laws.

As recognized in numerous final orders, the illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation. Preventing the diversion of list I chemicals into the illicit manufacture of methamphetamine is of critical importance in protecting the public from the devastation wreaked by this drug.

While the investigative file in this case contains no evidence establishing the risk of diversion by establishments such as those which Respondent proposed to distribute its products to, the firm's record of non-compliance with other federal laws does not inspire confidence in its willingness to faithfully obey DEA regulations. Here, the investigative file establishes two separate instances in which Respondent violated the FDA Act. Moreover, FDA found these violations well after the rule banning ephedrine alkaloids went into effect.

In section 303(h) of the CSA, Congress broadly directed that the Attorney General consider ''compliance by the applicant with applicable Federal, State, and local law,'' 21 U.S.C. 823(h)(2), in determining whether to grant a list I distributor's registration. In contrast to the provision applicable to a practitioner's registration, Congress did not limit the subject matter of the laws that are properly considered in determining whether an applicant's compliance record supports granting it a registration. *Cf. id.* § 823(f)(4) (directing consideration of a practitioner's ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances'').

Moreover, Respondent's apparent willingness to sell products which have been banned (as evidenced by the fact that banned products were found not once, but twice at its facility) and/or its inability to properly document its compliance with the FDA act (with respect to its assertion that it intended to export the products found in the first incident), are sufficiently probative of the manner in which it would likely fulfill its obligations as a registrant under the Controlled Substances Act.[1] I thus conclude that granting it a registration would ''be inconsistent with the public interest.'' *Id.* § 823(h).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) & 0.104, I order that the application of Respondent ATF Fitness Products, Inc., for a DEA Certificate of Registration as a distributor of list I chemicals be, and it hereby is, denied. This order is effective April 5, 2007.

Dated: February 23, 2007.

Michele M. Leonhart,

Deputy Administrator.

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[1] The CSA imposes extensive recordkeeping requirements on List I chemical distributors. See 21 CFR Pt. 1310.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Georgia Convenience Wholesale, Inc.; Denial of Application

On February 6, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Georgia Convenience Wholesale, Inc., (Respondent) of Doraville, Georgia. The Show Cause Order proposed to deny Respondent's pending application for a Certificate of Registration to distribute list I chemicals on the ground that its registration ''would be inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(h)).

The Show Cause Order specifically alleged that on April 19, 2005, Respondent applied for a registration to distribute list I chemicals including pseudoephedrine, ephedrine and phenylpropanolamine (PPA), and that these products ''are commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance.'' Show Cause Order at 1–2. The Show Cause Order alleged that Respondent was proposing to distribute these products to convenience stores, and that ''law enforcement officials have observed that an overwhelming proportion of precursors found at illicit methamphetamine sites have involved non-traditional pseudoephedrine and ephedrine brands sold through convenience stores.'' *Id.* at 2. The Show Cause Order also alleged that as non-traditional products ''become more tightly regulated, even traditional products are subject to diversion.'' *Id.*

The Show Cause Order further alleged that during a pre-registration investigation, Respondent's owner/operator was not aware that PPA had been withdrawn from the over-the-counter market. *Id.* Relatedly, the Show Cause Order alleged that Respondent had also sought registration for other list I chemicals even though these chemicals ''were not ingredients in any over-the-counter drug product.'' *Id.* Finally, the Show Cause Order alleged that Respondent ''does not have adequate experience or familiarity with products and the sales potentials in the industry to carry out the responsibilities of a registrant and prevent the diversion of listed chemical precursors into illicit activities.'' *Id.* at 3.

On or about February 24, 2006, the Show Cause Order, which also notified Respondent of its right to request a hearing, was served by certified mail,

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

Findings

Respondent is a Georgia corporation which is located at 4030 Pleasantdale Road, Doraville, Georgia. Respondent is a wholesale distributor of general merchandise to convenience stores, gas stations, candy stores, dollar stores, party stores, and liquor stores in the Atlanta, Georgia metropolitan area. Respondent has been in business since May 2005.

On April 19, 2005, Respondent's president, Mr. Mohammad S. Yaqoob, applied for a DEA Certificate of Registration to distribute list I chemicals. Specifically, Respondent applied to distribute ephedrine, methylephedrine, n-methlypseudoephedrine, norpseudoephedrine, phenylpropanolamine (PPA), and pseudoephedrine.

As explained in numerous DEA final orders, both pseudoephedrine and ephedrine currently have therapeutic uses. *See, e.g., Tri-County Bait Distributors*, 71 FR 52160, 52161 (2006).[1] Both chemicals are, however, regulated under the Controlled Substances Act because they are precursor chemicals which are easily extracted from non-prescription 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).

Methamphetamine is a powerful and highly addictive central nervous system stimulant. *See, e.g., Tri-County Bait Distributors*, 71 FR at 52161. The illegal manufacture and abuse of methamphetamine pose a grave threat to this country. Methamphetamine abuse has destroyed numerous lives and families and ravaged communities. Moreover, because of the toxic nature of the chemicals which are used to make the drug, the illegal manufacture of methamphetamine causes serious environmental harms. *Id.*

On June 9, 2005, two DEA Diversion Investigators (DIs) went to Respondent's proposed registered location to conduct a pre-registration investigation. The DIs met with Mr. Yaqoob, who informed the investigators that he had purchased the business on May 1, 2005. The DIs also met with Mr. Omar, Respondent's Vice-President.

Both Mr. Yaqoob and Mr. Omar told the DIs that each had previously owned a gas station and had sold list I chemical products. Mr. Yaqoob informed the DIs that Respondent's list I customers would be convenience stores and gas stations. Numerous DEA orders have found that these establishments are non-traditional (or gray market) retailers of list I chemical products. *See, e.g., T. Young Associates, Inc.*, 71 FR 60567, 60568 (2006).

Mr. Yaqoob also provided the DIs with a list of the list I chemical products Respondent intended to distribute. The list was comprised entirely of traditional cold and sinus medicines that contain pseudoephedrine. When one of the DIs asked Mr. Yaqoob why he had originally requested authorization to handle other list I chemicals, Mr. Yaqoob stated that he had not known exactly which drug codes were needed to handle pseudoephedrine so he asked for the additional codes. Mr. Yaqoob, however, had submitted a letter, which is dated prior to the onsite inspection, withdrawing Respondent's request to handle PPA, methylephedrine, n-methlypseudoephedrine, and norpseudoephedrine.

The investigation determined that Respondent's business is located in a large brick building which has an alarm system with motion detectors, glass break strips, and metal contact strips, and is monitored by a security company. Moreover, the doors were equipped with metal cross bars and dead bolt locks. Finally, the list I products were to be stored in a separate room (which was to remain locked at all times) and not in the warehouse. Furthermore, Respondent appeared to have adequate procedures for handling the list I products, as well as for identifying and verifying new customers.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute list I chemicals is entitled to be registered unless the registration would be ''inconsistent with the public interest.'' In making this 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.

''These factors are considered in the disjunctive.'' *Joy's Ideas*, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether an application for registration should be denied. *See*, *e.g.*, *David M. Starr*, 71 FR 39367 (2006); *Energy Outlet*, 64 FR 14269 (1999). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

In this case, I acknowledge that factors one, two, and three would not bar Respondent's registration. I find dispositive, however, that Respondent lacks relevant experience in the wholesale distribution of list I chemicals (factor four) and that it intends to distribute list I chemicals to the gray market (factor five), a market in which the risk of diversion is substantial. Consistent with DEA precedents, I hold that Respondent's registration would be inconsistent with the public interest.

Factor One—The Maintenance of Effective Controls Against Diversion

This investigative file does not establish that Respondent would fail to maintain adequate procedures to protect against diversion. Moreover, the file establishes that Respondent would provide adequate security of list I chemical products to protect them from theft. Thus, this factor does not support a finding that Respondent's registration would be inconsistent with the public interest.

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

There is no evidence that Respondent is not in compliance with applicable Federal, State, or local laws. Relatedly, there is no evidence that Respondent, or any person affiliated with it, has ever been convicted of a crime under either Federal or State laws relating to

[1] The FDA is, however, currently proposing to remove combination ephedrine-guaifenesin products from its over-the-counter (OTC) drug monograph and to declare them not safe and effective for OTC use. See 70 FR 40232 (2005).

controlled substances or listed chemicals. I thus conclude that neither factor supports a finding that Respondent's registration would be inconsistent with the public interest.

Factor Four—The Applicant's Past Experience in the Distribution of Listed Chemicals

DEA precedent establishes that ''an applicant's lack of experience in distributing list I chemicals creates a greater risk of diversion and thus weighs heavily against the granting of an application.'' *Tri-County Bait Distributors*, 71 FR at 52163. According to the investigative file, Respondent's president and vice-president previously owned gas stations at which they sold list I chemical products. But as I explained in *Tri-County Bait Distributors*, merely engaging in the retail sale of these products is not sufficient to establish that an applicant has experience which is relevant to fulfilling the regulatory obligations of a wholesaler of these products. *Id.*

Distributors of list I chemicals are subject to a comprehensive and complex regulatory scheme.*See* 21 CFR parts 1309 and 1310. Moreover, prior to the enactment of the Combat Methamphetamine Epidemic Act of 2005, retail distributors of ephedrine and pseudoephedrine were generally exempt from recordkeeping and reporting requirements.[2]

Accordingly, for an applicant's (or its key employee's) experience to be relevant, the key employee must have been actively involved in the fulfillment of a registrant's regulatory obligations as a wholesale distributor and demonstrate adequate knowledge of the applicant's proposed products.[3] Because neither of Respondent's key employees has such experience, I conclude that this factor supports a finding that granting it a registration would be inconsistent with the public interest.

[2] Effective September 30, 2006, retail distributors are now required to maintain a logbook which records the name and address of each purchaser of ephedrine or a pseudoephedrine product containing more than 60 mg. of the chemical, the date and time of the sale, the product name and the quantity sold.

[3] Respondent initially sought registration for additional chemicals beyond pseudoephedrine and ephedrine even though it intended only to carry products containing pseudoephedrine. According to the documentary evidence, Respondent withdrew its request to be registered for these chemicals before the inspection. Accordingly, I conclude that Respondent's initial request to be registered for the additional chemicals does not support a finding that it lacks adequate product knowledge.

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

Numerous DEA orders recognize that convenience stores and gas-stations constitute the non-traditional retail market for legitimate consumers of products containing pseudoephedrine and ephedrine. *See*, *e.g.*, *Tri-County Bait Distributors*, 71 FR at 52161; *D & S Sales*, 71 FR 37607, 37609 (2006); *Branex, Inc.*, 69 FR 8682, 8690–92 (2004). DEA orders also establish that the sale of list I chemical products by non-traditional 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 distributor] 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'').

Significantly, all of Respondent's proposed customers participate in the non-traditional market for ephedrine and pseudoephedrine products. DEA 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'' and ''substantial''); *Jay Enterprises, Inc.*, 70 FR 24620, 24621 (2005) (noting ''heightened risk of diversion'' should application be granted). Under DEA precedents, an applicant's proposal to sell into the non-traditional market weighs heavily against the granting of a registration under factor five. So too here.

Because of the methamphetamine epidemic's devastating impact on communities and families throughout the country, DEA has repeatedly denied an application when an applicant proposed to sell into the non-traditional market and analysis of one of the other statutory factors supports the conclusion that granting the application would create an unacceptable risk of diversion. Thus, in *Xtreme Enterprises*, 67 FR 76195, 76197 (2002), my predecessor denied an application observing that the respondent's ''lack of a criminal record, compliance with the law and willingness to upgrade her security system are far outweighed by her lack of experience with selling list I chemicals and the fact that she intends to sell ephedrine almost exclusively in the gray market.'' I have repeatedly adhered to this reasoning in denying applications to distribute list I chemicals to the non-traditional market. See, *e.g.*, Jay Enterprises, 70 FR at 24621; *Prachi Enterprises,* 69 FR 69407, 69409 (2004).

Here, Respondent's key persons have no experience in the wholesale distribution of list I chemical products and yet the firm intends to distribute these products to non-traditional retailers, a market in which the risk of diversion is substantial. *See Taby Enterprises of Osceola, Inc.*, 71 FR 71557, 71559 (2006). Given these findings, I hold that granting Respondent's application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) and 0.104, I order that the application of Georgia Convenience Wholesale, Inc., for a DEA Certificate of Registration as a distributor of list I chemicals be, and it hereby is, denied. This order is effective April 5, 2007.

Dated: February 23, 2007.

Michele M. Leonhart,

Deputy Administrator.

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