

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

MK Distributing, Inc.; Denial of Application

On May 25, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to MK Distributing (Respondent) of Arvada, Colorado. The Show Cause Order proposed to deny Respondent's pending application for a DEA Certificate of Registration as a distributor of list I chemicals, on the ground that its registration would be inconsistent with the public interest. See Show Cause Order at 1 (citing 21 U.S.C. 823(h)).

More specifically, the Show Cause Order alleged that on November 18, 2003, Respondent's owner, Frederick H. Gates, had applied for a registration to distribute ephedrine and pseudoephedrine, which are precursor chemicals used in the illicit manufacture of methamphetamine. *Id.* at 1–2. The Show Cause Order alleged that Respondent's customer base "is comprised primarily of gas stations, convenience stores, and independent grocers," and that these establishments are "sources for the diversion of listed chemical products." *Id.* at 2.

The Show Cause Order further alleged that on April 1, 2003, Mr. Gates had purchased Respondent and that between that date and October 2003, Respondent had distributed 18,351 bottles and 3,720 packets of combination ephedrine (25 mg) products under the DEA registration of its previous owner. *Id.* at 2–3. The Show Cause Order alleged that Mr. Gates' use of the previous owner's registration violated DEA regulations that prohibit the assignment or transfer of a registration without the written consent of the Administrator. *Id.* at 3 (citing 21 CFR 1309.63).

The Show Cause Order also alleged that between May and October 2003, Respondent sold 1,056 bottles and 672 packets of ephedrine to the Barn Store, a small independent grocer, and that these sales were "far in excess of legitimate demand for these products." *Id.* Relatedly, the Show Cause Order alleged that during the same period, Respondent sold 849 bottles and 312 packets of ephedrine products to a combination gas station/convenience store, and that these sales were also "far in excess of legitimate demand for these products." *Id.* The Show Cause Order thus concluded by alleging that all of Respondent's customers are part of the non-traditional market for list I

chemical products, that its sale of these products "is inconsistent with the known legitimate market and * * * end-user demand for [these] products," and that granting its application "would likely lead to increased diversion of list I chemicals." *Id.* at 4.

On June 6, 2005, 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

Methamphetamine and the List I Chemical Market

Both ephedrine (in combination with guaifenesin) and pseudoephedrine currently have therapeutic uses and are generally available as non-prescription products.¹ See *Tri-County Bait Distributors*, 71 FR 52160, 521612 (2006). Both chemicals are, however, regulated under the Controlled Substances Act because they 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 addictive central nervous system stimulant. See *Gregg Brothers Wholesale Co.*, 71 FR 59830 (2006). 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 used to make the drug, its manufacture causes serious environment harms.² *Id.*

In numerous cases, DEA has shown through expert testimony that only a

¹ Combination ephedrine-guaifenesin products are currently approved for use as a bronchodilator for the treatment of asthma. The FDA is, however, currently proposing to remove these 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).

² According to the investigative file, in 2002, law enforcement agencies seized 452 illicit methamphetamine laboratories in Colorado.

small percentage of pseudoephedrine sales occur at gas stations and convenience stores and that these stores constitute a non-traditional market for the legitimate commerce in these products. See, e.g., *T. Young Associates, Inc.*, 71 FR 60567, 60568 (2006); *D & S Sales*, 71 FR 37607, 37608–09 (2006); *Branex, Inc.*, 69 FR 8682, 8690–92 (2004). DEA has further established that the monthly expected sales of combination ephedrine products by non-traditional retailers such as convenience stores and gas stations to meet legitimate demand, i.e., the purchase of the products for their medically approved use as a bronchodilator to treat asthma, is between \$0 and \$25, with an average of \$12.58. See, e.g., *T. Young Associates, Inc.*, 71 FR at 60567 n.2 & 60568 (2006); *Tri-County Bait Distributors*, 71 FR 52160, 52161–62 (2006); *D & S Sales*, 71 FR 37607, 37608–09 (2006). DEA has also shown that a monthly retail sale of \$60 to meet legitimate consumer demand for ephedrine products "would occur about once in a million times in random sampling." *T. Young*, 71 FR at 60568 (int. quotations and citations omitted).

Findings Pertinent to Respondent

Respondent is a Colorado corporation which is located at 6150 W. 55th Avenue, Arvada, Colorado. On November 18, 2003, Respondent's owner, Mr. Frederick H. Gates, submitted an application for a registration to distribute the list I chemicals ephedrine and pseudoephedrine. Respondent is a wholesaler of pornographic magazines, DVDs, videos, toys and novelty items in the Colorado Springs area. Respondent's customer base is largely comprised of non-traditional retailers of list I chemical products. See, e.g., *T. Young Associates, Inc.*, 71 FR at 60568.

Respondent was previously owned by Mike and Jane Kleppen, who incorporated the firm in November 2001; this entity held a DEA registration to distribute list I chemicals which was last renewed on December 9, 2002. According to the investigative file, on April 1, 2003, the Kleppens sold the business to either Mr. Gates or another firm owned by him. The Kleppens did not, however, surrender MK Distributing's DEA registration.

Between April 1, 2003, and October 8, 2003, Respondent continued to distribute large quantities of combination ephedrine products using the registration issued to MK Distributing under its previous owners. On the latter date, two DEA Diversion Investigators (DIs) went to MK

Distributing's warehouse and met with Jane Kleppen. The DIs questioned Ms. Kleppen as whether the new owners had obtained a DEA registration. Ms. Kleppen advised the DIs that on April 1, 2003, MK Distributing had been purchased by a firm called "Pleasures," and that the latter firm had not applied for a DEA registration because of its inability to obtain a tax identification number.

The DIs informed Ms. Kleppen that the new company was not authorized to use the registration. One of the DIs then asked Ms. Kleppen to voluntarily surrender the DEA registration; Ms. Kleppen agreed and signed a voluntary surrender form. Ms. Kleppen then surrendered the list I products that were in Respondent's warehouse.

Ms. Kleppen told the DIs that the original certificate of registration was at her residence and that there were additional list I products on Respondent's four delivery vans. Accordingly, the following day, the DIs returned to Respondent and obtained the original certificate from Ms. Kleppen. Ms. Kleppen then turned over to the DIs additional list I products, which were subsequently returned to the supplier.

As stated above, on November 18, 2003, Mr. Gates (Respondent's new owner) applied for a registration. On July 1, 2004, the same two DIs returned to Respondent's warehouse to conduct a pre-registration investigation. During this visit, Mr. Gates told the DIs that he expected that list I products would be approximately ten percent of Respondent's total sales. When asked what ephedrine was used for, Mr. Gates told the DIs that it was used by truck drivers to stay alert, for weight loss, and methamphetamine.

As part of the application process, Respondent was required to complete a questionnaire. On this questionnaire, Mr. Gates stated that "[t]he new owners of MK Distributing, LLC[,] have sold 18,351 bottles of Ephedrine 25 mg, and 3,720 packets of ephedrine 25 mg before DEA investigators * * * pulled" the registration. Mr. Gates also provided a list of the monthly purchases of list I products by Respondent's customers from May through October 2003.

A representative sampling of this information shows that Respondent was selling massive amounts of combination ephedrine products to its gas station/convenience store customers.³ Between May and September, Respondent sold 720 bottles (for a monthly average of

144) to the Kwik-Way Dublin, 960 bottles (for a monthly average of 192) to the Corner Store, and 654 bottles (for a monthly average of 130.8) to Lil T Foods. During the same period, Respondent sold 1147 bottles (for a monthly average of 229.4) to the Broken Wheel, 1200 bottles (for a monthly average of 240) to PHA, and 692 bottles (for a monthly average of 138.40) to Centron. Finally, Respondent sold 828 bottles (for a monthly average of 165.60) to R & S, 768 bottles (for a monthly average of 153.6) to the South Circle Station, and 993 bottles (for a monthly average of 198.6) to the Conoco Union gas station.

According to the investigative file, the DIs were told by an employee at one store that the retail price of the sixty-count bottles was \$7.99. This figure is consistent with other information that DEA has obtained during investigations in Colorado. *See Wild West Wholesale*, 72 FR 4042, 4043 (2007) (finding that retail price was \$5.99 for 48-count combination ephedrine product).

At an average retail price of \$7.99 per bottle, the monthly average sales of the above stores were: Kwik-Way Dublin, \$1151; Corner Store, \$1534; Lil T Foods, \$1045; Broken Wheel, \$1833; PHA, \$1918; Centron, \$1106; R & S, \$1323; South Circle, \$1227; and Conoco Union, \$1587.⁴ The average monthly sale for all of these stores was \$1414. As explained above, through expert testimony, DEA has established that the monthly expected sales range of combination ephedrine products at a non-traditional retailer to meet legitimate consumer demand is between \$0 and \$25, with an average of \$12.58; a monthly retail sale of \$60 to meet legitimate consumer demand at a non-traditional retailer would occur about once in a million times in random sampling.

Because these sales so greatly exceed the monthly expected sales range to meet legitimate demand, I further find that most of Respondent's products were diverted into the illicit manufacture of methamphetamine. Moreover, even if these stores sold Respondent's products at a lower retail price (such as the price found in *Wild West Wholesale* for a smaller quantity), I would still find that Respondent's sales were so excessive that its products were diverted.

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 conclude that an analysis of factors one, two, and three is not necessary. I hold that factors four (Respondent's experience) and five (Respondent's intent to distribute to the non-traditional market) conclusively establish that granting Respondent's application would be inconsistent with the public interest.

Factors Four and Five—The Registrant's Past Experience in the Distribution of Chemicals and Other Factors Relevant To and Consistent With Public Health and Safety

As found above, the illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation. Cutting off the supply source of methamphetamine traffickers is of critical importance in protecting the public from the devastation wreaked by this drug.

While combination ephedrine products have a legitimate medical use as a bronchodilator to treat asthma, DEA orders have established that convenience stores and gas-stations constitute the non-traditional retail market for legitimate consumers of products containing ephedrine. *See, e.g., Tri-County Bait Distributors*, 71 FR

³ All of the data used in the sampling were for sixty-count bottles. Respondent also sold ephedrine packets to several of these entities.

⁴ These figures were either rounded up or down to the nearest dollar.

at 52161; *D & S Sales*, 71 FR at 37609; *Branex, Inc.*, 69 FR at 8690–92. DEA has further found 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).

DEA orders thus recognize that the sale of combination ephedrine (and pseudoephedrine) 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, Inc.*, 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”).⁵ Here, nearly all of Respondent’s customers are convenience stores and gas stations, which are non-traditional retailers of list I chemical products; DEA has repeatedly found that these entities are conduits for the diversion of list I products into the illicit manufacture of methamphetamine.

Relatedly, DEA has repeatedly revoked the registrations of list I chemical distributors who supplied the non-traditional market for selling quantities of products that clearly exceeded legitimate demand and were likely diverted into the illicit manufacture of methamphetamine. *See T. Young Associates, Inc.*, 71 FR at 60572–73; *D & S Sales*, 71 FR at 37611–

12; *Joy's Ideas*, 70 FR at 33198–99; *Branex, Inc.*, 69 FR at 8693–96. Most significantly, the investigative file establishes that Respondent distributed combination ephedrine products in quantities that far exceeded legitimate consumer demand for these products as an asthma treatment.

The representative sampling of Respondent’s customers showed that the lowest average estimated monthly retail sale per store was \$ 1045; four of the stores had average monthly retail sales of more than \$ 1500. Moreover, the average estimated monthly sale for all stores in the sample was \$ 1414. These figures grossly exceed the monthly expected sales range of \$ 0 to \$ 25 (with an average of \$ 12.58) by convenience stores to meet legitimate demand for these products. *See T. Young*, 71 FR at 60568; *D & S Sales*, 71 FR at 37609.

Indeed, as found above, a monthly retail sale of \$ 60 of ephedrine products at a convenience store should “occur about once in a million times in random sampling.” *T. Young*, 71 FR at 60568. The \$ 1414 average monthly retail sale for all nine stores is more than twenty-three times this amount. Moreover, this figure is an average for these stores over a five-month period. It is thus considerably more improbable than a one in a million probability that Respondent’s products were being purchased to meet legitimate demand.

I therefore conclude that the only plausible explanation for these extraordinary sales is that Respondent’s products were being diverted into the illicit manufacture of methamphetamine. *See T. Young*, 71 FR at 60572; *D & S Sales*, 71 FR at 37611 (finding diversion occurred “[g]iven the near impossibility that * * * sales were the result of legitimate demand”); *Joy's Ideas*, 70 FR at 33198 (finding diversion occurred in the absence of “a plausible explanation in the record for this deviation from the expected norm”). Moreover, because the purpose of the CSA’s registration provisions is to protect the public interest, it is irrelevant whether Respondent knew that its products were being diverted. *T. Young*, 71 FR at 60572.

“The diversion of list I chemicals into the illicit manufacture of methamphetamine poses the same threat to public health and safety whether a registrant sell the products knowing they will be diverted, sells them with a reckless disregard for the diversion, or sells them being totally unaware that the products were being diverted.” *Id.* (citing *D & S Sales*, 71 FR at 37610–12, & *Joy's Ideas*, 70 FR at 33198). As I have previously noted (albeit in a revocation proceeding), the

public interest standard does not require that the Government prove that a registrant acted with any particular *mens rea* in order to support a finding that diversion has occurred. *T. Young*, 71 FR at 60572. The same rule applies to an applicant who has previously engaged in the distribution of list I products. Accordingly, where, as here, substantial quantities of products have been diverted, adverse findings are warranted under factors four and five even if Respondent’s owner was unaware that its products were being diverted. I therefore hold that granting Respondent’s application would be inconsistent with the public interest.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h), as well as 28 CFR 0.100(b) & 0.104, I order that the application of MK Distributing, 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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DEPARTMENT OF LABOR

Employment Standards Administration

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment Standards Administration is soliciting comments concerning the proposed collection: Notice of Law Enforcement Officer’s Injury or Occupational Disease (CA–721) and Notice of Law Enforcement Officer’s Death (CA–722). A copy of the proposed

⁵ *See OTC Distribution Co.*, 68 FR 70538, 70541 (2003) (noting “over 20 different seizures 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”).