Form	Burden estimate per form (*in minutes*)	Number of *respondents*	Annual burden on respondents (*in hours*)
On-site survey	15	1,250	313
Telephone survey	15	500	125
Total	.....	1,750	438

Comments

A notice allowing the public a 60-day comment period was published in the **Federal Register** on May 2, 2006 (71 FR 25857, May 2, 2006). No comments were received in response to the 60-day comment period. The Public now has a second chance to comment.

Comments are Invited on

(a) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical use;

(b) the accuracy of our burden estimate for the proposed collection of information, including the validity of the methodology and assumptions used;

(c) ways to enhance the quality, usefulness, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Reclamation will display a valid OMB control number on the survey forms.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Michael R. Finnegan,

Area Manager, Central California Area Office, Mid-Pacific Region.

[FR Doc. E7–4406 Filed 3–9–07; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–22]

Planet Trading, Inc., d/b/a/ United Wholesale Distributors, Inc.; Denial of Application

On February 15, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Planet Trading, Inc., (Respondent) of Orlando, Florida. The Show Cause Order proposed to deny Respondent's pending application for a DEA Certificate of Registration as a distributor of the list I chemicals ephedrine and pseudoephedrine on the ground that Respondent's registration would be inconsistent with the public interest. Show Cause Order at 1, *see also* 21 U.S.C. 823(h).

More specifically, the Show Cause Order alleged that both ephedrine and pseudoephedrine are ''commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance.'' Show Cause Order at 1. The Show Cause Order alleged that ''DEA knows by experience'' that a ''gray market'' exists ''in which certain pseudoephedrine and ephedrine products are distributed only to convenience stores and gas stations, from where they have a high incidence of diversion'' into the illicit manufacture of methamphetamine. *Id.* at 2. Relatedly, the Show Cause Order alleged that only ''[a] very small percentage'' of legitimate sales of list I chemical products occur in gray market retailers and that the average gray market retailer ''could expect to sell * * * only about $10.00 to $30.00 worth of pseudoephedrine products'' a month. *Id.* at 3. The Show Cause Order also alleged that the expected sales for combination ephedrine products are ''only one-fourth of'' this amount. *Id.*

The Show Cause Order alleged that during a pre-registration investigation, Respondent's president advised DEA investigators that his firm distributes sundry items and tobacco products to convenience stores, gas stations, and small independent groceries, which constitute the gray market for list I chemical products. *Id.* at 2. The Show Cause Order further alleged that during an interview, Respondent stated that he had ''little or no background in handling list I chemical products.'' *Id.* The Show Cause Order also alleged that Respondent told the investigators that he intended to sell list I products that were marketed in bottles and not blister packs because the latter ''were not good sellers.'' *Id.*

The Show Cause Order also alleged that Respondent intended to store the list I products in a warehouse ''with all other items [and] without any additional security installed.'' *Id.* at 3. The Show Cause Order further alleged that ''[b]ecause [Respondent's] customers are allowed to serve themselves from the warehouse shelves, all customers will have unescorted access to the list I chemicals stored in the warehouse.'' *Id.*

Finally, the Show Cause Order alleged that Respondent's ''proposed sales of combination ephedrine and pseudoephedrine products are inconsistent with the known legitimate market and known end-user demand for products of this type,'' and thus Respondent ''would be serving an illegitimate market for [these] product[s].'' *Id.* The Show Cause Order concluded by alleging that because Respondent's owner had ''no experience handling list I chemicals'' and its warehouse has ''insufficient security,'' its ''registration would likely lead to increased diversion of list I chemicals.'' *Id.*

Respondent, through its owner Mr. Vihang Patel, requested a hearing. The case was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing in Tampa, Florida, on November 1, 2005. At the hearing, both parties put on witnesses and introduced documentary evidence. Following the hearing, the Government submitted proposed findings of fact and conclusions of law.

On April 25, 2006, the Administrative Law Judge submitted her decision which recommended that Respondent's application be denied. Neither party filed exceptions. The record was then forwarded to me for final agency action.

Having considered the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's decision in

its entirety and conclude that Respondent's registration would be inconsistent with the public interest. I therefore order that Respondent's application be denied.

Findings

Respondent, a Florida corporation, sells sundry items and tobacco products to convenience stores, gas stations, and small independent groceries. Respondent does not make deliveries. Rather, it operates a walk-in warehouse which is located in an Orlando, Florida industrial park. Respondent's President is Mr. Vihang Patel; Mr. Patel and his two brothers each own one-third of the corporation. *See* ALJ Dec. at 9–10.

On August 27, 2003, Mr. Patel applied on Respondent's behalf for a DEA Certificate of Registration to distribute list I chemicals. Gov. Ex. 1. As relevant here, Respondent sought the registration to distribute pseudoephedrine and ephedrine.[1] *Id.*

Methamphetamine and the Market for List I Chemicals

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).[2] 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., see also* Tr. 12.

The illicit manufacture of methamphetamine is an increasing problem in the State of Florida. According to the testimony of a DEA Special Agent, during the period October 1, 2004, through September 30, 2005, law enforcement authorities seized 340 clandestine laboratories statewide. Tr. 10–11. A DEA Diversion Investigator (DI) further testified that the illicit manufacture of methamphetamine is an especially serious problem in central Florida and the panhandle. *Id.* at 26.

The record further establishes that there is both a traditional market and a non-traditional (or gray) market for pseudoephedrine and ephedrine products. According to the declaration of Jonathan Robbin, who has testified as an expert on statistical analysis of these markets in numerous proceedings, pseudoephedrine products sold in the traditional market typically contained 30 mg. of the chemical, are manufactured ''in combination with other active ingredients,'' and are sold in blister packs of 24, 36, or 96 count. Gov. Ex. 10, at 3–4. Ephedrine products sold in the traditional market typically contain 12.5 mg. of ephedrine and 200 mg. of guaifenesin and are sold in boxes of either 24 or 60 tablets. *Id.* at 4. By contrast, the products sold in the non-traditional market typically contain 60 mg. of pseudoephedrine, which is not combined with any other active ingredient, and are sold in bottles containing 60, 100, and 120 tablets. *Id.* at 5; *see also* Gov. Ex. 6, at 12. Moreover, the ephedrine products sold in the non-traditional market typically contain 25 mg. of ephedrine combined with 200 mg. of guaifenesin and are sold in bottles containing 60 tablets. Gov. Ex. 10, at 6.

According to the Government's expert witness, who has examined both the 1997 and 2002 United States Economic Censuses, approximately 97 percent of all non-prescription drugs are sold in pharmacies, supermarkets, large discount and general merchandise stores, or through electronic shopping/mail order houses. *Id.* at 4. The data also show that non-prescription drug sales accounted for only 2.6% (in the 2002 Economic Census) ''of the overall sales of all convenience stores that handle'' these products and only 0.6% of the total sales of convenience stores. *Id.* at 4–5. The Government's expert further testified that the sale of pseudoephedrine products comprise ''only about 2.6% of the [Health and Beauty Care] category of merchandise or 0.05% of total in-store (non-gasoline) sales that occur at convenience stores. *Id.* The Government's expert further stated that combination ephedrine products ''have about half the over-the-counter sales volume'' of pseudoephedrine products. *Id.* According to the Government's expert, the normal expected sales range to meet legitimate demand for pseudoephedrine products at a non-traditional retailer is ''between $0 and $40 per month, with an average of $20.60''; the expected sales range for combination ephedrine products at a convenience store is ''between $0 and $25, with an average of $12.58'' per month. *Id.* at 8.

Finally, the Government's expert recounted numerous instances in which wholesale distributors sold massive quantities of pseudoephedrine and ephedrine products to convenience stores and other non-traditional retailers. *See id.* at 8–14. The expert further concluded that the massive sales of these products cannot be explained by persons buying them for non-FDA approved uses such as ''weight loss or energy enhancement.'' *Id.* at 16. As the Government's expert concluded, DEA has found that these massive sales are ''indicative of diversion to illicit use.'' *Id.* at 17.

According to DI Mark J. Rubbins, who served as Chief of the Domestic Chemical Control Unit of the Office of Diversion Control, ''[n]on-traditional stores * * * tend to knowingly sell [list I products] in large quantities to 'smurfers.' '' Gov. Ex. 6, at 6. DI Rubbins further explained that smurfers ''are groups of individuals affiliated with methamphetamine traffickers that frequent these establishments at different times or on different dates, with the aim of buying out a store's supply of over-the-counter medications.'' *Id.* at 6–7.

DI Rubbins further testified that certain list I products have been ''disproportionately represented in clandestine lab seizures around the United States.'' *Id.* at 12. The pseudoephedrine products are Mini Thin, Mini Twin, Unique, Action-Pseudo, Revive, OTC-Pseudo, and Twin-Pseudo; the ephedrine products are Max Brand, Xtreme, Xtreme Relief Dual, Mini Two-Way, and Max Brand *Id.* at 11–12. In addition, the brand names MinTwin 2-Way and Heads-Up are used to sell both pseudoephedrine and ephedrine tablets. *Id.* at 12. With respect to the pseudoephedrine products, DI Rubbins stated that these products are preferred by illicit methamphetamine producers because pseudoephedrine is their only active ingredient and they are packaged in ''large bottle sizes.'' *Id.* Moreover, blister packs are not preferred by methamphetamine producers because it is more ''time consuming'' to extract the product from its packaging. Tr. 35.

[1] Respondent also sought to distribute phenylpropanolamine (PPA), a product which is the subject of an FDA rulemaking which proposes to reclassify the drug as not generally safe and effective. *See* 70 FR 75988, 75994 (2005). Respondent no longer seeks registration to distribute PPA products.

[2] 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).

The Pre-Registration Investigation and Respondent's Testimony

On January 27, 2004, a DI visited Respondent's facility and met with Mr. Vihang Patel, Respondent's president, to conduct a pre-registration investigation. Tr. 29. During the inspection, Mr. Patel provided the DI with a list of the list I chemicals products his firm intended to sell. Gov. Ex. 5.The list included numerous products that are preferred by illicit methamphetamine producers including bottle sizes of Ephedrine Two-Way, MiniThin Two-Way, and Max Brand Two-Way.[3] *Id.* at 2. Additionally, the list included a number of products that do not contain list I chemicals such as Goody Powder, Goody Body Pain Powder, BC Arthritis Powder, and BC Powder. *Id.* at 1. Moreover, at the hearing Mr. Patel demonstrated a general lack of knowledge as to whether particular products contained either pseudoephedrine or ephedrine. When asked during cross-examination whether certain products (Nyquil, Dayquil, Tylenol Cold, Tylenol Sinus, Tylenol Allergy, Advil Cold, Tylenol PM) contained pseudoephedrine, Mr. Patel answered: ''I'm not sure if any one of them does or not. We have to * * * go to the chemical contents, or ingredients of that particular product.'' Tr. 106. When asked whether any of these products contained ephedrine, Mr. Patel stated: ''I think they do.'' *Id.* at 107. However, none of the products contain ephedrine.

During the inspection, Mr. Patel told the DI that ''he would be selling bottles'' and that ''he would not be selling blister packs because his customers didn't like them or want them.'' *Id.* at 50. At the hearing, however, Mr. Patel testified that he was no longer interested in selling gray market products but only traditional allergy and cold medicines such as Nyquil and Tylenol Sinus. *Id.* at 91, 96.

Mr. Patel also told the DI that he had been ''an aeronautical engineer for eleven years,'' and that he ''had minimal experience'' in selling listed chemicals. *Id.* at 38. According to the record, Respondent's experience involved working on weekends in a similar business owned by his family that is located in Lakeland, Florida. *Id.*

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, 39368 (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 two and three would not bar granting Respondent a registration. I conclude, however, that Respondent lacks effective controls against diversion (factor one), lacks relevant experience in the distribution of list I chemicals (factor four), and 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 thus hold that Respondent's registration would be inconsistent with the public interest.

Factor One—Maintenance of Effective Controls Against Diversion

I concur with the ALJ that the Government has not proved that Respondent would fail to provide adequate physical security for the list I chemicals stored at its facility. However, '' 'prior agency rulings have applied a more expansive view of factor one than mere physical security.' '' *D & S Sales*, 71 FR 37607, 37610 (2006) (quoting *OTC Distribution Co.*, 68 FR 70538, 70542 (2003)). A registrant is ''required to exercise a high degree of care in monitoring its customers' purchases'' of list I chemical products to prevent diversion. *Id.* Relatedly, DEA has repeatedly revoked the registrations of list I chemical distributors 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 60567, 60572–73 (2006); *D & S Sales*, 71 FR at 37611–12; *Joy's Ideas*, 70 FR at 33198–99; *Branex, Inc.*, 69 FR 8682, 8693–96 (2004).

Here, I conclude that it is likely that Respondent would not properly monitor its customers' purchases. Both during the pre-registration investigation and at the hearing, Respondent's president demonstrated a lack of familiarity with OTC drug products. During the pre-registration investigation, he represented that certain products contained list I chemicals when they did not. At the hearing, he did not know which products contained which chemicals and again referred to products (Tylenol PM and Tylenol Arthritis) that do not contain either ephedrine or pseudoephedrine as if they did. Respondent's president further admitted that he would have to check the ingredients of the particular product to be sure of whether it contained a list I chemical. In short, his lack of such basic product knowledge does not inspire confidence that his firm would know which products must be monitored to ensure that they were not being purchased in excessive quantities and being diverted into the illicit manufacture of methamphetamine. I thus conclude that this factor support a finding that granting Respondent a 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. Furthermore, 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 controlled substances or listed chemicals. I thus conclude that both factors weigh in favor of granting Respondent's application.

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 record, Respondent itself has no experience in distributing list I chemicals. The ALJ found, however,

[3] Ephedrine Two-Way tablets are manufactured by ProActive Labs Inc.; MiniThin Two-Way tablets are manufactured by B.D.I. Pharmaceutical. Gov. Ex. 5, at 2. Because of the extent to which these products have been found in illicit methamphetamine labs, DEA has sent numerous warning letters to both of these firms. *See D & S Sales*, 71 FR 37607, 37608 (2006).

that Respondent's president does have ''some limited experience'' working on weekends at another firm which distributes list I chemicals. ALJ Dec. at 15.

Distributors of list I chemicals are subject to a comprehensive and complex regulatory scheme. *See* 21 CFR Pts. 1309 & 1310. Moreover, as I explained in *Tri-County Bait Distributors*, merely working as a sales clerk does not establish that an applicant has relevant experience. 71 FR at 52163. Rather, for an applicant's (or its key employee's) experience to be relevant, the applicant must have been actively involved in the fulfillment of a registrant's regulatory obligations and demonstrate adequate knowledge of list I products.

While this standard may not have been clear at the time of the hearing, I nonetheless conclude that a remand is unnecessary. As explained above (and as the ALJ found), Respondent's president ''has little knowledge of which products on his proposed product list contained ephedrine or pseudoephedrine.'' ALJ Dec. at 15–16. Thus, even if Respondent's president had established that he had performed regulatory obligations, his lack of knowledge of basic product information would still lead me to conclude that his experience was inadequate. I thus hold that this factor supports a finding that Respondent's registration would be inconsistent with the public interest.

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 at 37608–09; *Branex, Inc.*, 69 FR at 8690–92. 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, Inc.*, 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 seizures of [gray market distributor's] pseudoephedrine product at clandestine sites,'' and that in an 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, Inc.*, 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.'' More recently, I have denied applications explaining that an applicant's ''lack of a criminal record and any intent to comply with the law and regulations are far outweighed by his lack of experience and the company's intent to sell ephedrine and pseudoephedrine exclusively to the gray market.'' *Jay Enterprises*, 70 FR at 24621. *Accord Prachi Enterprises, Inc.*, 69 FR 69407, 69409 (2004).

Here, Respondent clearly lacks effective controls against diversion, its key employee has only limited experience in the wholesale distribution of list I chemical products during which he apparently learned very little about the products he seeks to carry, and yet it intends to distribute these products to non-traditional retailers, a market in which the risk of diversion is substantial.[4] *See Taby Enterprises of Osceola, Inc.*, 71 FR 71557, 71559 (2006). Given these findings, it is indisputable 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) & 0.104, I order that the application of Planet Trading, Inc., d/b/a United Wholesale Distributors, 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 11, 2007.

Dated: February 28, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 07–1103 Filed 3–9–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

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 pre-clearance 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

[4] Initially, Respondent also sought to sell high strength, high count list I products including several brands that DEA has frequently found during seizures of illicit methamphetamine laboratories. *See* Gov. Exh. 5, at 2. *See also OTC Distribution*, 68 FR at 70541, *MDI Pharmaceuticals*, 68 FR at 4236. At the hearing, however, Respondent expressed a willingness to carry only smaller packages of traditional cold and allergy medicines. *See* ALJ Dec. at 11. For the reasons stated above, I nonetheless conclude that the Government has shown that Respondent's registration would be inconsistent with the public interest.