DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–16]

T. Young Associates, Inc.; Revocation of Registration; Introduction and Procedural History

On December 17, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to T. Young Associates of Hermitage, Tennessee (Respondent). The Show Cause Order proposed to revoke Respondent's DEA Certificate of Registration, 004395TSY, as a distributor of List I chemicals, and to deny any pending applications for renewal or modification of the registration, on the ground that Respondent's registration is inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(h). *See* 21 U.S.C. § 824(a)(4).

The Show Cause Order alleged in substance that on July 31, 2001, Respondent applied for a modification of its registration as a List I chemical distributor requesting registration to handle and distribute phenylpropanolamine, ephedrine and pseudoephedrine at a new location. *See* Show Cause Order at 2. The Show Cause Order further alleged that Respondent sells primarily ''gray market products'' to convenience stores and gas stations, that Respondent's owner had informed DEA Diversion Investigators (DIs) that List I chemical products amounted to approximately nine percent of his total sales, and that some of the manufacturers of the products sold by Respondent have received warning letters from DEA because the products were found during law enforcement seizures of clandestine laboratories. *See id.* The Show Cause Order further alleged that Tennessee led DEA's southeast region in the number of illicit methamphetamine laboratory seizures, that most illegal methamphetamine is produced locally, and that methamphetamine production continues unabated. *See id.* at 2–3.

The Show Cause Order further alleged that DEA had engaged an expert in the field of retail marketing and statistics who had studied the purchases of List I chemical products by hundreds of Tennessee retailers and concluded that these stores were purchasing these products in amounts that were far in excess of legitimate demand. *See id.* at 4. The Show Cause Order alleged that small illicit laboratories procure the precursor chemicals required to manufacture methamphetamine from non-traditional retailers such as gas stations and small retail markets and that some of these retailers use multiple distributors to mask their acquisition of large amounts of listed chemicals. *See id.*

Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing in Nashville, Tennessee, on September 28 and 29, 2004. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, but before the record was closed, the Government introduced into evidence the affidavit of its expert witness, Mr. Jonathan Robbin. Respondent then submitted into evidence his own affidavit addressing the issues raised in the Robbin affidavit, as well as several other exhibits. Following the closing of the record, both parties submitted post-hearing briefs.

On October 28, 2005, the ALJ submitted her decision recommending that Respondent's registration be revoked. Neither party filed exceptions. The record was then transmitted 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 findings of fact and conclusions of law except as expressly noted herein. For the reasons set forth below, I concur with the ALJ's recommendation that Respondent's registration be revoked. I further order that any pending applications for renewal or modification of Respondent's registration be denied.

Findings

Respondent is a corporation whose shares are owned entirely by Mr. Roy T. Young. Respondent is the holder of DEA Certificate of Registration, 004395TSY, which authorizes it to distribute the List I chemicals phenylpropanolamine, ephedrine and pseudoephedrine.[1] Respondent, which is located in Hermitage, Tennessee, sells a variety of general merchandise and nonfood items such as ball caps, sunglasses, cigarette lighters, novelty items and licensed athletic wear to predominately gas stations and convenience stores in eastern and middle Tennessee. Mr. Young testified that Respondent ''did a couple of million dollars a year by the early 2000s.'' Tr. 233. Mr. Young further testified that ephedrine was ''about nine or ten percent of my sales in the chain stores.'' *Id.* at 290. Mr. Young also testified that he had decided not to carry pseudoephedrine although he did sell it ''from time to time'' to certain customers. *Id.* at 240.

Methamphetamine and the Market for List I Chemicals

While both ephedrine and pseudoephedrine have therapeutic uses,[2] they are also precursor chemicals that are regulated by the Controlled Substances Act. *See* 21 U.S.C. 802(34). Moreover, these chemicals are easily extracted from legal and what typically were over-the-counter products [3] and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. *See* 21 CFR 1308.12(d).

Methamphetamine ''is a powerful and addictive central nervous system stimulant.'' *D & S Sales*, 71 FR 37607, 37608 (2006). The illegal manufacture and abuse of methamphetamine pose a grave threat to this country. Methamphetamine abuse has destroyed numerous lives and families and has ravaged communities. Moreover, because of the toxic nature of the chemicals used in producing the drug, illicit methamphetamine laboratories cause serious environmental harms. According to the testimony of DEA Special Agent Guy Hargreaves, Staff Coordinator for the DEA Methamphetamine Program at DEA Headquarters, in 1999 there were 101 explosions and at least 64 fires at clandestine labs throughout the United States. *See* Gov. Exh. 26, at 9. Moreover, the annual cost to government agencies to clean up methamphetamine labs is ''millions of dollars.'' *Id.* at 10.[4]

The problem of methamphetamine abuse is especially serious in Tennessee. According to the record, the number of law enforcement seizures of clandestine laboratories in Tennessee rose from 106 in 1999 to ''over 700 labs'' in 2003. *See* ALJ at 8, Tr. at 14. Moreover, according to a DEA Special Agent, as of September 28, 2004 (the date of the hearing), there

[1] There is no evidence in the record that Respondent had distributed phenylpropanolamine.

[2] According to the affidavit of Mr. Douglas A. Snyder, a Drug Science Officer within the Drug and Chemical Evaluation Section in the Office of Diversion Control, under the Food, Drug and Cosmetic Act's provisions pertaining to over-the-counter (OTC) products, ephedrine is lawfully marketed as a bronchodilator used to treat asthma. Govt. Exh. 27, at 3–4. Pseudoephedrine is lawfully marketed under the Food, Drug and Cosmetic Act's OTC provisions as a decongestant. *See id.* at 4.

[3] In response to the methamphetamine epidemic, many States have enacted legislation making pseudoephedrine a Schedule V drug under State controlled substances acts.

[4] According to the Suspicious Order Task Force, as of 1998 the cost to clean up a small boxed lab site was $30,000. *See* Gov. Exh. 28, at 18.

had been close to 700 seizures in Tennessee already that year.[5] Tr. at 14.

A DEA Special Agent who serves in the Nashville office as a clandestine lab enforcement agent testified that, based on his observations of products found at clandestine lab sites, as well as interviews he had conducted with various defendants, there was a trend of methamphetamine cooks obtaining List I chemicals from ''smaller gas stations and convenience stores.'' *Id.* at 12. According to the Special Agent, he had been told in the interviews that meth. cooks were ''able to buy cases, half cases, and such out the back door of'' convenience stores and gas stations. *Id.* The Special Agent further testified that some meth. cooks drive around to different stores with four or five different addicts who go into several stores in different cities and purchase sub-threshold quantities of List I chemicals.

The Government submitted into evidence the affidavit of Mark J. Rubbins, a Diversion Investigator who was then assigned as Chief of the Domestic Chemical Control Unit, Office of Diversion Control, DEA Headquarters. According to DI Rubbins, DEA has determined that there is both a traditional and non-traditional market for List I chemical products. *See* Gov. Exh. 44, at 5. The traditional market is characterized by a short chain of distribution. In this market, manufacturers either sell directly to large chains of grocery stores (such as Giant and Safeway), pharmacies (such as Rite Aid and CVS), and other larger retailers (such as Wal-Mart), or they sell to large wholesalers (such as Bergen Brunswig and AmeriSource). *See id.* at 5–6. Furthermore, List I chemical products sold in this market are typically of lower strength and lower count sizes such as 30 mg. pseudoephedrine tablets in small, blister pack sizes of six, twelve, twenty-four and sometimes forty-eight count. *See id.* at 5.

In contrast, products sold in the non-traditional market pass through multiple layers of distribution and are sold by such establishments as gas stations, small convenience stores, liquor stores, headshops, beauty parlors, and video stores. *See id.* at 6. Moreover, the products are typically stronger than those found in the traditional market and include 60 mg. pseudoephedrine tablets which are sold in larger package sizes such as 60, 100, or 120 count bottle sizes. DI Rubbins further stated that non-traditional retailers tend to knowingly sell large quantities of List I chemical products to ''smurfers,'' individuals who work for methamphetamine traffickers and attempt to buy out a store's entire stock of List I chemical products by going to the store at different times or on different days. *See id.* at 6–7.

DI Rubbins stated that because of increased DEA enforcement efforts involving pseudoephedrine products, methamphetamine traffickers have increasingly gone back to using combination ephedrine products. *See id.* at 10. DI Rubbins further stated that in 2002, he contacted the major manufacturers of combination ephedrine/guaifenesin products and determined that sales for these products amounted to only one-tenth of the market for legitimate single-entity pseudoephedrine products. *See id.* According to DI Rubbins, the names of products that are popular with methamphetamine traffickers are ''MiniThin'' and ''Mini Twin,'' which each contain 60 mg. pseudoephedrine, and ''Max Brand'' and ''Mini Two Way,'' which are combination ephedrine products. *See id.* at 12. Mr. Rubbins further stated that these brands ''have been disproportionately represented in clandestine lab seizures around the United States involving listed chemical products.'' *Id.* at 13.

The Government also submitted the affidavit of John Uncapher, who was then assigned as a Staff Coordinator with the Domestic Operations Division at DEA Headquarters. Mr. Uncapher's staff was responsible for the DEA Warning Letter program. *See* Gov. Exh. 42, at 3. Under this program, DEA collects information regarding List I chemicals products that have been found at clandestine lab sites and identifies the manufacturers of these products. *See id.* The Government entered into evidence a list of 35 warning letters issued to PDK Laboratories, the manufacturer of Max Brand, a product which Respondent distributes. *See* Gov. Exh. 19. According to this exhibit, between January 5, 1999, and September 26, 2002, approximately 1.67 million pseudoephedrine tablets and 107,250 combination ephedrine tables manufactured by this firm were found in numerous seizures of clandestine laboratories throughout the United States including Tennessee. The Government also introduced into evidence a list of 17 warning letters issued to BDI because their products, which Respondent also distributed, were found during seizures of clandestine laboratories. *See* Gov. Exh. 20.

The Government submitted into evidence the declaration of Jonathan Robbin, an expert in statistical analysis of demographic, economic, geographic and survey data. Based on his study of the latest available United States Economic Census of Retail Trade, Mr. Robbin concluded that ''over 97% of all sales of non-prescription drug products occur in drug stores and pharmacies, supermarkets, large discount merchandisers and electronic shopping and mail order houses.'' Gov. Exh. 70, at 4. Moreover, sales of non-prescription drugs by convenience stores (including both those that sell and do not sell gasoline), ''account for only 2.2% of the overall sales of all convenience stores that handle the line and only 0.7% of the total sales of all convenience stores.'' *Id.*

Mr. Robbin further testified that based on his study of U.S. Government Economic Census Data, information obtained from the National Association of Convenience Stores, and commercially available point of sale transaction data, he constructed a model of the traditional market for retail sales of pseudoephedrine. *See id.* at 5. According to Mr. Robbin, sales of pseudoephedrine account for ''only about 2.6%'' of the sales of health and beauty care products in convenience stores and only ''0.05% of total in-store (non-gasoline) sales.'' *Id.*

Mr. Robbin testified that ''the normal expected retail sale of pseudoephedrine (Hcl) tablets in a convenience store may range between $0 and $40 per month, with an average of $20.60 per month.'' *Id.* at 7. Mr. Robbin also testified that ''the expected sale of ephedrine (Hcl) tablets in a convenience store ranges between $0 and $25, with an average of $12.58.'' *Id.* at 7–8. Mr. Robbin further testified that a monthly retail sale of $40 of ephedrine or $60 of pseudoephedrine would ''occur less than one in 1,000 times in random sampling.'' *Id.* Moreover, a monthly retail sale of $60 of ephedrine or $100 in pseudoephedrine would ''occur about once in a million times in random sampling.'' *Id.*

The Investigation of Respondent

Respondent's initial registered location was 1319 Central Court, Hermitage, Tennessee. On July 19, 2001, Mr. Young wrote a letter to DEA's Nashville office informing it that Respondent had relocated its warehouse to 1320 Central Court, Hermitage, Tennessee, and requesting that DEA issue a registration for the new address. *See* Gov. Exh. 3. According to Mr. Young's testimony, Respondent had leased both the 1319 and 1320 locations

[5] As noted in *Gregg Brothers Wholesale Co., Inc.*, 71 FR 59830 (2006), in 2004, law enforcement agencies seized 939 clandestine labs in Tennessee.

for some period. When Respondent's lease for the 1319 location came up for renewal, Mr. Young decided to terminate it and vacate the premises as he was already leasing the 1320 space and had leased another premises (4706 Lebanon Pike) which he was using for an office and retail store. *See* Tr. 242–43. Mr. Young did not notify DEA, however, until after Respondent moved out of its then registered location. *Id.* at 244–45.

Because DEA's regulations provide that a ''request for modification shall be handled in the same manner as an application for registration,'' 21 CFR 1309.61, on August 7, 2001, two DIs visited Respondent's 1320 Central Court facility to conduct an investigation. ALJ at 15. The DIs inspected the facility and obtained from Respondent lists of both its customers and suppliers. The DIs found that the List I chemical products were securely stored in a locked area of the warehouse. *See id.*

The DIs told Mr. Young that they would conduct an accountability audit. The DIs conducted an inventory of all List I chemical products on hand and obtained Mr. Young's signature on their inventory report. Tr. 39–40. The DIs also told Mr. Young that they needed to know what inventory was on Respondent's delivery trucks. *Id.* at 40. One of the DIs could not recall, however, whether Mr. Young had said there were List I chemical products on the trucks. *Id.* at 41. The DI later testified that Mr. Young had never gotten back to them regarding List I chemicals that may have been on the trucks. *Id.* at 131. In his testimony, Mr. Young confirmed that the DIs had asked him about ''the truck inventory'' and whether there were any ''inventories on the truck.'' *Id.* at 254.

The DIs then requested the invoices necessary to conduct an accountability audit. Mr. Young told the DIs that the records were not kept at the warehouse but were at his office, which was located at 4706 Lebanon Pike.[6] The DIs then went to the office. *Id.* at 37.

The DI proceeded to perform a 30 day accountability audit[7] of three of the products—Ephedrine Plus 60 tablet bottles, Max Brand 60 tablet bottles, and Nyquil two tablet packets. Because there was no beginning inventory, the DIs assigned a value of zero for each of the products. *Id.* at 47. The DIs then examined both the hard copy purchase invoices from Respondent's suppliers and Respondent's hard copy sales records.[8] *Id.* at 51, 147. The audit determined that there were overages in the amount of 3,131 Ephedrine Plus bottles and 600 NyQuil packets. Gov. Exh. 12. The audit also found a shortage of 26 bottles of Max Brand Ephedrine. *Id.*

The ALJ found that ''[t]he investigators did not contact Mr. Young to discuss the audit results'' and noted that ''Mr. Young testified that he was not aware of the audit results until three years after the August 7, 2001 visit.'' ALJ at 17.[9] The ALJ further found that Mr. Young then had his employees go back through his records and recalculate Respondent's sales; the employees found overages. *See id.; see also* Tr. 257–58.

In October 2001, DEA modified Respondent's registration by changing the address of his registered location to 1320 Central Court. The DI testified that he had granted the modification because of the financial hardship Mr. Young was undergoing in maintaining three separate premises. Tr. at 33.

Approximately a year after the on-site inspection, one of the DIs conducted verification visits of three of Respondent's customers. ALJ at 18. The manager at each location verified that the store was a customer of Respondent; each of the managers also told the DI that they used more than one supplier of List I chemicals. *See id.* At two of the stores, the managers told the DI that they were attempting to identify customers who they believed were purchasing List I chemical products for illicit use and report them to law enforcement authorities. *See id.*

On September 19, 2003, Mr. Young requested another modification of the registration to change both the name on the registration and the address of its registered location to 4706 Lebanon Pike. On December 17, 2003, however, the instant Show Cause Order was issued. *See* ALJ at 17.

On February 20, 2004, two DIs and a Special Agent visited Respondent at its Lebanon Pike location to deliver a letter from Howard Davis, the Diversion Program Manager for DEA's Atlanta Field Division. The letter instructed Respondent that he could not store listed chemicals at his new proposed location until DEA approved the change. Gov. Exh. 46. The letter further explained that DEA would not approve any modification until the Order to Show Cause was resolved. *Id.*

During the visit, Mr. Young told one of the DIs that no List I chemicals were being stored at the Lebanon Pike location. However, during the visit, one of the DIs found a display rack containing 24 bottles and 5 packets of ephedrine products on a shelf in the office. ALJ at 17. Because the products were at a non-registered location, the DI immediately seized them. *Id.*

Mr. Young testified that the products were at the Lebanon Pike location because his son had taken them there to photograph them for a brochure to be used in marketing them to Respondent's customers. Tr. 277. Mr. Young testified that after the pictures were taken the products should have been immediately returned to the truck. *Id.* at 278.

As part of DEA's investigation, one of the DIs obtained from Respondent's suppliers copies of invoices documenting its purchases of List I chemical products from January 2003 through July 2004. Tr. at 166–75. According to the invoices from one supplier, CB Distributors, Respondent purchased 5,616 bottles of Rapid Action (60 tablet count), 576 bottles of Rapid Action (48 tablet count), 10,850 packets of Rapid Action (12 tablet count), 3,168 bottles of Mini Two Way (60 tablet count), 576 bottles of Mini Two Way (48 tablet count), 3,456 packets of Mini Two Way (6 tablet count), 15,708 bottles of Max Brand 2-Way (60 tablet count), 17,280 packets of Max Brand 2-Way (6 tablet count), and 1,584 bottles of Twin Tabs (60 tablet count). ALJ at 18.

The Government also introduced two invoices it had received from another of Respondent's suppliers, Sasser Distributing. The invoices show that on July 27, 2004, Respondent purchased 288 bottles of ephedrine products (60 tablet count); the next day, Respondent purchased another 144 bottles of Biotek Ephedrine (48 tablet count), as well as an additional amount of Ephedrine Plus

[6] The DIs further informed Mr. Young that under Federal regulations, records of purchases over certain amounts must be maintained at the registered location. *See* Tr. 37–38. The record contains an invoice documenting a purchase from PDK Laboratories of 720 bottles containing 60 tablets of 2 way ephedrine, a product that contains 25 mg. of ephedrine hydrochloride per tablet. *See* Gov. Exh. 6. Respondent's purchase of this product did not, however, exceed the one kilogram threshold. *See* 21 CFR 1310.04(f)(1); Gov. Exh. 23.

[7] The audit actually covered the period from July 1, 2001, through August 7, 2001. *See* Gov. Exh. 12.

[8] There was a factual dispute as to whether Respondent informed the DIs as to the existence of his computerized records. The ALJ found that ''whatever computerized records Respondent maintained showed only the dollar amount of the sale but not the products sold; this latter information was shown only on hard copy invoices.'' ALJ at 15; *see also* Tr. at 252. Because the accountability audit was based on the quantity and not dollar amount of the products, the dispute is immaterial.

[9] There is, however, conflicting testimony by Mr. Young that when the DIs were through with the audit, ''we sat down and had a short meeting out front, then a reference was made to a large overage in one category'' and I told the DIs ''you can't honestly be over.'' Tr. at 253.

packets (6 tablet count). See Gov. Exhs. 52–53.[10]

As stated above, the Government entered into evidence the affidavit of Jonathan Robbin. According to the affidavit, DEA provided Mr. Robbin with a list of 801 wholesale transactions involving combination ephedrine and pseudoephedrine products made by Respondent to 97 Tennessee convenience stores between January 27, 2003, and November 22, 2004. Gov. Exh. 70, at 12. The affidavit further stated that during this period Respondent sold 17,271 bottles, each containing 60 tablets, and 24,520 packages, each containing six tablets, of combination ephedrine products. *See id.* The bottles held a total of 1,036,260 tablets and the packets held a total of 147,120 tablets. *Id.* Respondent also sold to 31 convenience stores, 1,435 bottles, each containing 60 tablets of Max Brand 30 mg. pseudoephedrine, for a total of 86,100 tablets of pseudoephedrine products. *Id.*

Using this data, Mr. Robbin calculated each store's implied average monthly retail sales and compared that to the normal expected retail sales discussed above.[11] *See id.* at 13. According to Mr. Robbin, only one of the 97 stores was selling near the normal expected sales range at 2.8 times expectation. *Id.* at 15. The next lowest store was selling over 20 times the expected sales range. *Id.* Mr. Robbin explained that in random sampling, sales over 20 times expectation ''could occur only about three times in a billion raised to the fifth power.'' *Id.* Mr. Robbin further explained that ''[t]he probability of an index equal to or greater than 20 is so small as to be near impossibility.'' *Id.* at 16. Finally, Mr. Robbin found that the top 94 stores had indexes over 25, the top 54 stores sold ''over 100 times expectation,'' and the top sixteen sold ''over 300 times expectation.'' *Id.* at 16.

Mr. Robbin explained that ''[s]uch indexes are not possible in the normal commerce of these goods at ordinary convenience stores.'' *Id.* According to Mr. Robbin, because the average convenience store serves 120,000 shoppers per year, if combination ephedrine products were being purchased by customers to treat asthma (the purpose for which the FDA has approved them), three million persons would have to shop at the store in a year to account for sales 25 times the expected amount. *Id.* Mr. Robbin further explained that while it was possible that a single customer could purchase a store's entire monthly inventory, this amount of product would supply the person with enough of the drug to treat an asthmatic condition at recommended doses for two and one-quarter years. *Id.* Mr. Robbin explained that ''[i]t is difficult to imagine * * * what such a shopper would do with all of this material every month except to resell or use it as a precursor chemical in the illicit manufacture of methamphetamine.'' *Id.* at 16–17. Mr. Robbin thus concluded that Respondent ''frequently sells combination ephedrine * * * and single ingredient pseudoephedrine * * * products to these stores in extraordinary excess of normal or traditional demand by ordinary convenience store shoppers.'' *Id.* at 17.

Mr. Young submitted an affidavit challenging the factual basis of Mr. Robbin's findings. According to Mr. Young, he supplied records covering only the 365 day period from September 2003 through August 2004. Resp. Exh. 19, at 1. Mr. Young further stated that ''the total number of stores serviced fluctuate[d] and was not a hard and fast 97 stores as stated by Mr. Robbin.'' *Id.*

Mr. Young also challenged Mr. Robbin's findings as to the monthly expected sales range of combination ephedrine and pseudoephedrine products in convenience stores. Mr. Young asserted that according to the March 28, 2005 edition of Convenience Store News, ''the average c-store sold $5,462 worth of cold and cough remedies in 2003.'' *Id.* Mr. Young also asserted that according to the National Association of Convenience Stores State of the Industry Report for 2003, ''the average c-store sold $2,980 of cough & cold remedies in 2003.'' *Id.* at 2. Mr. Young thus contends that ''[t]hese independent studies show average monthly sales of $250 to $450 per store per month for the c-store industry. This amount is 8 to 14 times greater than what Robin [sic] reports.'' *Id.* Mr. Young further asserted that Respondent's average per store sales of combination ephedrine products ''is within the norms for the sale of these products to convenience stores that we have experienced in the 14 years that we have been in business.'' *Id.* at 4.

In support of his affidavit, Mr. Young also submitted into evidence a spreadsheet showing its List I chemical sales from September 2003 through August 2004. *See* Resp. Exh. 20. According to the spreadsheet, Respondent sold a total of $68,568.11 of List I chemical products to an average of 54 stores per month. *See id.* The spreadsheet also indicates that Respondent's average sale per store, per month, was $105.81, and calculates that the average retail sale per store, per month, was $184.00. *Id.* The spreadsheet also indicates that Respondent's sales of traditional branded products (such as Advil, Aleve, Tylenol, Dayquil and Nyquil that contain pseudoephedrine) amounted to only $1,507 out of the total of $68,568, or approximately two percent of its List I chemical product sales. *Id.*

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a List I chemical ''may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. § 824(a)(4). 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. § 823(h).

• 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 a registration should be revoked or an application for a modification of a 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. *DE*A, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). My analysis of the factors in this case compels the conclusion that Respondent's continued registration would be inconsistent with the public interest.

[10] During the August 2001 on-site inspection, the DIs received a supplier list from Mr. Young. Tr. 56. One of the DIs determined that at least two of Respondent's suppliers had received warning letters from DEA. ALJ at 18.

[11] Mr. Robbin's affidavit explains in detail his methodology, including the figure he used for the products' gross margin, to calculate the implied retail sales value of the products.

Factor One—Maintenance of Effective Controls Against Diversion

I acknowledge that Respondent provides effective security against the theft of listed chemicals. Accurate recordkeeping is, however, another important control against diversion. *See* 21 CFR 1309.71(b)(8). As to this system, the record clearly indicates that Respondent does not maintain effective controls against diversion.

The accountability audit found that two of the products sold by Respondent had overages; the other product had a shortage. As the ALJ noted, the DIs used a zero opening inventory for each product because Respondent did not have an inventory. Using a zero opening inventory will result in an over-count if, in fact, a registrant had product on hand on the beginning date of the audit period. I note, however, that Mr. Young testified that he had his employees go back through his records and they too came up with overages. Tr. 257–58.

The DIs also found that there was a shortage of 26 Max Brand 60 tablet bottles. This is especially significant because the audit covered only a short period of time (approximately five weeks). Moreover, if, in fact, Respondent had product on hand on the beginning date of the audit period, assigning an inventory of zero would result in an undercount of the shortage.

I further note the testimony regarding whether there was inventory on the trucks. The ALJ noted that there was ''somewhat inconsistent testimony about whether some List I chemicals were on'' the trucks. *See* ALJ at 22. I am satisfied, however, that the DIs asked Respondent whether there were any List I chemicals on the trucks, *see* Tr. 40 and 254, and the fact remains that Respondent had no readily obtainable records showing the amount of inventory, if any, that was on the trucks. I therefore conclude that Respondent does not maintain effective controls against diversion. This factor thus supports a finding that Respondent's continued registration would be inconsistent with the public interest.

Factor Two—Compliance with Applicable Federal, State, and Local Laws

The record here demonstrates that Respondent committed several violations of Federal law and regulations. First, in July 2001, Respondent moved its List I chemicals from the 1319 Central Court building, which was its registered location, to the 1320 Central Court building, without obtaining approval from DEA. This action violated 21 U.S.C. § 822(e) and 21 CFR 1309.23(a).

The ALJ also found that Respondent violated 21 CFR 1310.04(c), by storing List I chemical records at its Lebanon Pike location, which was not registered. *See* ALJ at 23. The record does not, however, support this finding. While 21 CFR 1310.04(c) requires that records be maintained ''at the regulated person's place of business where the transaction occurred,'' *id.*, the provision applies only to records which must be maintained under 21 CFR 1310.03. The only provision of that section which is pertinent here is the requirement that a regulated person keep a record of ''a regulated transaction.'' *Id.* § 1310.03(a). The regulations establish that the threshold for transactions in combination ephedrine products between wholesale distributors is one kilogram. *Id.* § 1310.04(f)(1)(ii); *see also* Comprehensive Methamphetamine Control Act of 1996, Pub. L. No. 104–237, § 401(f), 110 Stat. 3099, 3110 (1996) (adopting one kilogram threshold for regulated transactions in combination ephedrine products between wholesale distributors).

The record contains only a single invoice conceivably documenting a regulated transaction between Respondent and one of its suppliers, PDK Laboratories, which had occurred at the time of the August 2001 inspection. This invoice indicates that on July 17, 2001, Respondent purchased 720 bottles containing 60 combination ephedrine tablets of 25 mg. ephedrine hydrochloride for a total of 43,200 tablets. *See* Gov. Exh. 6. This amount of product does not, however, exceed the one kilogram threshold because the hydrochloride constitutes approximately 18 percent of the chemical. As the Government's own exhibit demonstrates, the one kilogram threshold was equivalent to 48,826 combination ephedrine hcl tablets each containing 25 mg. ephedrine hcl. *See* Gov. Exh. 23. Because Respondent's purchase was more than 5,000 tablets under this amount, and there is no other evidence indicating that Respondent engaged in additional purchases during the month, the record does not establish that Respondent violated 21 CFR 1310.04(c).

The record does, however, contain evidence establishing an additional violation of DEA regulations. During the February 2004 visit, the DIs found a display rack containing 24 bottles and 5 packets of combination ephedrine products at Respondent's Lebanon Pike store/office. Because Respondent's Lebanon Pike facility was not a registered location, Respondent's storage of the items at this location violated 21 U.S.C. § 822(e) and 21 CFR 1309.23(a). Most remarkably, Respondent committed this second violation after having been served with a Show Cause Order.

Because Respondent committed multiple violations of the CSA's provisions, I conclude that Respondent's record of compliance with Federal law supports a finding that its continued registration would be inconsistent with the public interest.

Factor Three—The Record of Criminal Convictions

The record contains no evidence that Respondent's owner, or any employee, has been convicted of an offense under laws related to either controlled substances or listed chemicals. I thus conclude that this factor supports a finding that Respondent's continued registration would not be inconsistent with the public interest.

Factor Four—Past Experience in Distributing Listed Chemicals

It is undisputed that Respondent has distributed List I chemical products for several years. That experience is, however, characterized by several violations of the CSA, as well as the inability of Respondent to provide an accurate accounting of its products. Moreover, as described under factor five below, there is substantial evidence in the record establishing that Respondent's products have been diverted. Accordingly, this factor supports a finding that Respondent's continued registration would be inconsistent with the public interest.

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

The record here establishes—as do numerous agency precedents—that there is a substantial nexus between the sale of certain non-traditional List I chemical products by non-traditional retailers and the diversion of these products into the illicit production of methamphetamine. *See, e.g., John Vanags*, 71 FR 39365, 39366 (2006); *Joey Enterprises,* 710 FR 76866, 76887 (2005); *TNT Distributors,* 70 FR 12729, 12730 (2005). Indeed, as noted recently in *TNT Distributors,* which also involved a Tennessee-based distributor of List I chemicals, ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores.'' 70 FR at 12730.

Likewise in this case, there is undisputed testimony by a DEA Special

Agent establishing that Tennessee-based methamphetamine cooks were purchasing large quantities of List I chemicals from smaller stores such as gas stations and convenience stores. Tr. at 12. Respondent's List I chemical sales were principally made to these types of retail establishments.

Moreover, Respondent's Exhibit 20, which was a compilation of its sales of List I chemical products for the period September 2003 through August 2004, establishes that 98 percent of its sales were of non-traditional products including those of several manufacturers who have received warning letters from this agency because their products have frequently been found during seizures of clandestine methamphetamine labs. Respondent's Exhibit 20 further establishes that during this period, its average sale per store, per month, was $105.81, which would result in an average retail sale per store, per month, of $184.

The ALJ found ''persuasive'' the affidavit of Mr. Robbin, the Government's expert witness who testified about the market for List I chemical products. ALJ at 23. Based on this evidence, the ALJ further concluded that ''Respondent sold quantities of List I chemicals to convenience stores that far exceeded what the stores could reasonably be expected to sell to legitimate consumers.'' *Id.* The ALJ also rejected Mr. Young's assertion in his post-hearing affidavit challenging Mr. Robbin's testimony as to the normal expected sales of combination ephedrine and pseudoephedrine products in convenience stores. *See id.* According to Mr. Young, the average convenience store sold between $250 and $450 per store, per month, an amount that ''is 8 to 14 times greater than what Robin [sic] reports.'' Resp. Exh. 19, at 2.

As the ALJ observed, combination ephedrine products cannot be lawfully marketed over-the-counter as a cold and cough remedy and most of Respondent's sales were of this type of product. *See* ALJ at 23; 21 CFR 341.76. Moreover, products containing pseudoephedrine are only a subset of over-the-counter cold remedies. Respondent has produced no evidence establishing the percentage of over-the-counter cold remedies that include pseudoephedrine. I therefore credit Mr. Robbin's expert testimony as to the normal expected sales ranges of both ephedrine combination and pseudoephedrine products in non-traditional retailers.

Mr. Young also challenged the factual basis for Mr. Robbin's findings that were based on data supplied to the latter by DEA. According to Mr. Robbin's affidavit, the findings that were specific to Respondent were based on ''a list supplied to the DEA by T. Young of 801 wholesale transactions drawn from invoices to 97 convenience stores in Tennessee,'' which covered the period from January 27, 2003, through November 22, 2004. Govt. Exh. 70, at 12. Mr. Robbin further stated that the ''[d]ata given for each transaction included invoice date, store name, a product description and number of units sold.'' *Id.* at 13. Mr. Young asserts, however, that he supplied DEA with ''data from September 2003 thru August 2004,'' that the data ''was for 365 days, not for 665 and the total number of stores serviced fluctuate[d] and was not a hard and fast 97 stores as stated by Mr. Robbin.'' Resp. Exh. 19, at 1.

The ALJ did not address this factual dispute. Mr. Robbin's declaration makes clear that he did not review the actual invoices but rather data provided him by the Government. The Government did not, however, submit into evidence the list of transactions referred to by Mr. Robbin or the documentary evidence upon which the list was based. Moreover, while Mr. Young clearly provided data to DEA regarding Respondent's sales, *see* Resp. Exh. 19, at 1, the Government did not elicit any testimonial evidence from a witness with personal knowledge of how the list was obtained that establishes the scope of the data contained therein and refutes Respondent's contention. Accordingly, while I have credited Mr. Robbin's testimony regarding the expected sales ranges for combination ephedrine products and pseudoephedrine in non-traditional retailers, I do not adopt his findings that were based on Respondent's sales.

Respondent's own evidence nonetheless demonstrates that it sold List I chemical products to non-traditional retailers in quantities that far exceeded legitimate demand and thus supports a finding that its products were diverted. During the period of September 2003 through August 2004, Respondent sold at wholesale prices an average of $ 105.81 to each store, each month. *See* Resp. Exh. 20, at 1. By Respondent's calculation, these List I chemical products produced an average retail sale of $184 per store, per month. *See id.*[12]

Mr. Robbin found as a general matter that the expected retail sales range of ephedrine (Hcl) in a convenience store is ''between $0 and $25, with an average of $12.58.'' Govt. Exh. 70 at 8. Mr. Robbin further found that a monthly retail sale of ''$60 of ephedrine (Hcl) tablets would be expected to occur about once in a million times in random sampling.'' *Id.* By Respondent's own calculation, its customers' average monthly retail sale of ephedrine products was several times this amount. Moreover, this average was based on 54 stores over a twelve month period. It is thus even more improbable (than a one in a million probability) that these sales were to meet legitimate consumer demand for these products. I therefore conclude that a preponderance of the evidence establishes that a substantial portion of Respondent's products were diverted. *See 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'').

That Respondent may have lacked any intent to divert or to sell to customers who were diverting to the illicit manufacture of methamphetamine (*See* Resp. Br. 8) is irrelevant. ''In determining the public interest,'' Congress granted the Attorney General broad discretion to consider any other factor that is ''relevant to and consistent with the public health and safety.'' 21 U.S.C. § 823(h)(5). The statutory text imposes no requirement that the Government prove that a Registrant has acted with any particular *mens rea.* Indeed, the diversion of List I chemicals into the illicit manufacture of methamphetamine poses the same threat to public health and safety[13] whether a registrant sells the products knowing they will be diverted, sells them with a reckless disregard for the diversion, *See D & S Sales,* 71 FR at 37610–12, or sells them being totally unaware that the products were being diverted. *Cf. Joy's Ideas,* 70 FR at 33198 (revoking registration notwithstanding that distributor was ''an unknowing and unintentional contributor to [the] methamphetamine problem.'').[14]

[12] While this figure is an average, it is unlikely that all stores bought right at the average. Some stores bought less, some bought more.

[13] In contrast to the provision pertaining to practitioners, the public interest determination applicable to List I chemical distributors does not limit the Attorney General's discretion to considering only those factors that ''threaten public health and safety.'' *Compare* 21 U.S.C. § 823(h)(5) *with id.* § 823(f)(5) (''such other factors as are relevant to and consistent with public health and safety''). The discussion in the text to the threat caused by the diversion of List I chemicals is used only to demonstrate the point that a registrant's *mens rea* is irrelevant.

[14] Mr. Young asserts that ''[t]he average per store sales of all ephedrine products to our stores is within the norms for the sale of these products to

Respondent points to the testimony of the DI who conducted verification visits of three of Respondent's customers. According to Respondent, this establishes that ''respondent's customers conscientiously keep[] track of the materials sold and report[ ] any excess sales to local police.'' Resp. Br. at 6. The record establishes, however, that the verification visits involved only a small fraction of Respondent's customers and thus this testimony does not refute the finding that its products were diverted.

Respondent further asserts that following Tennessee's enactment of the Meth-Free Tennessee Act of 2005, as well as new laws in Georgia and Kentucky, revoking his registration would be ''an arbitrary overreaching act'' because the new laws restrict the products that can be sold by non-traditional retailers to those in gel-cap or liquid form and he is selling only these products. Resp. Br. 7. DEA is already aware, however, of several studies showing that methamphetamine can be produced from List I chemicals sold as liquid-filled gel caps and liquids. *See* Drug Enforcement Administration, *Microgram Bulletin* 96–97,102 (June 2005) (discussing studies conducted by Washington State Patrol Crime Laboratory and McNeil Consumer and Specialty Pharmaceuticals). Moreover, experience has taught DEA that in the aftermath of every major piece of legislation addressing the illicit manufacture of methamphetamine, traffickers have quickly found ways to circumvent the restrictions.

Moreover, even assuming that Respondent will fully comply with the Tennessee and Kentucky laws, the Georgia statute would apparently not prohibit Respondent from selling combination ephedrine products to non-traditional retailers. *See* Georgia Code § 16–13–30.3 (allowing convenience stores to sell ephedrine products). Respondent would also be able to distribute products to non-traditional retailers in other States which have not imposed similar restrictions. Therefore, I conclude that factor five supports a finding that Respondent's continued registration would be inconsistent with the public interest.

In sum, Respondent has committed several violations of the CSA. *See* 21 U.S.C. § 823(h)(2). Moreover, Respondent has no effective means of accounting for List I chemical products. *Id.* § 823(h)(1). Finally, the record establishes that Respondent sold large amounts of non-traditional products into the non-traditional or ''gray market,'' a market which DEA has repeatedly found to be a substantial source for diversion, and the statistical improbability that these sales were to meet legitimate consumer demand supports a finding that the products were diverted into the illicit manufacture of methamphetamine. *Id.* § 823(h)(5). *See also Joy's Ideas,* 70 FR at 33199; *Branex, Inc.,* 69 FR 8682, 8693 (2004); *Xtreme Enterprises, Inc.,* 67 FR 76195, 76197 (2002). Thus, it is clear that continuing Respondent's registration would be inconsistent with the public interest.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. § 823(h) & § 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, 004395TSY, issued to T. Young Associates, Inc., be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective November 13, 2006.

Dated: September 14, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 06–8193 Filed 10–12–06; 8:45 am]

BILLING CODE 4410–09–P

convenience stores that [his firm has] experienced in the 14 years that we have been in business,'' and that these figures predate the methamphetamine problem. Resp. Ex. 19. at 4. The ALJ did not, however, credit this testimony. Moreover, Respondent did not produce any documentary evidence establishing its sales levels prior to the emergence of the methamphetamine epidemic in Tennessee. Thus, to the extent this testimony was offered to show that Respondent's more recent sales were consistent with the traditional and legitimate demand for List I chemical products and therefore rebut a finding that diversion occurred, I decline to credit it. To the extent the testimony was offered to show that Respondent did not intend that it products be diverted, it is irrelevant.

LEGAL SERVICES CORPORATION

Notice of Intent To Award—Grant Awards for the Provision of Civil Legal Services to Eligible Low-Income Clients Beginning January 1, 2007

AGENCY: Legal Services Corporation.

ACTION: Announcement of intention to make FY 2007 Competitive Grant Awards.

SUMMARY: The Legal Services Corporation (LSC) hereby announces its intention to award grants and contracts to provide economical and effective delivery of high quality civil legal services to eligible low-income clients, beginning January 1, 2007.

DATES: All comments and recommendations must be received on or before the close of business on November 13, 2006.

ADDRESSES: Legal Services Corporation—Competitive Grants, Legal Services Corporation; 3333 K Street, NW., Third Floor; Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Reginald Haley, Office of Program Performance, at (202) 295–1545, or *haleyr@lsc.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to LSC's announcement of funding availability on April 17, 2006 (71 FR 19758), and Grant Renewal applications due on June 15, 2006, LSC intends to award funds to the following organizations to provide civil legal services in the indicated service areas. Amounts are subject to change.

Service area	Applicant name	Grant amount
	Alabama	
AL–4	Legal Services Alabama, Inc	$5,775,139
MAL	Texas RioGrande Legal Aid, Inc	29,577
	Alaska	
AK–1	Alaska Legal Services Corporation	668,572
NAK–1	Alaska Legal Services Corporation	487,216