comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to *pubcomment-ees.enrd@usdoj.gov*, or mailed to: P.O. Box 7611, U.S. Department of Justice, Washington, D.C. 20044–7611, and should refer to: *U.S.* v. *Temrac Company, Inc.*, DJ. Ref. 90–11–2-07484/3.

The Consent Decree may be examined at U.S. EPA Region III, Office of Regional Counsel, 1650 Arch Street, Philadelphia, PA 19103–2029, c/o Gail Wilson, Esq. During the public comment period, the Consent Decree may also be examined at the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the Settlement Agreement may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $5.25 (25 cents per page reproduction cost), or $ 6.50 for the Consent Decree and the attached exhibits, payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Robert Brook,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 05–13 and 05–45]

Sunny Wholesale, Inc.; Revocation of Registration and Denial of Application

On August 24, 2005, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Sunny Wholesale, Inc. (Respondent), of Forest Park, Georgia. ALJ Ex. 6. The Order immediately suspended Respondent's DEA Certificate of Registration, No. 004550SLY, which authorizes it to distribute the list I chemicals ephedrine and pseudoephedrine, on the ground that it was selling ''excessive amounts'' of these chemicals to convenience stores, *id.* at 6, which are the ''primary source'' for the diversion of these chemicals into the illicit manufacture of methamphetamine, a schedule II controlled substance.[1] *Id.* at 4.

More specifically, the Show Cause Order alleged that in July 2005, DEA Diversion Investigators (DIs) learned that records seized from various north Georgia convenience stores which were ''suspected of illegally distributing listed chemical precursors,'' had ''indicated that [Respondent] had been distributing 60 count bottles of'' Max Brand pseudoephedrine, a product which has been repeatedly found at illicit methamphetamine labs ''in full case and double case lots.'' *Id.* at 6. The Show Cause Order alleged that ''law enforcement officials [in Tennessee and Georgia] have observed that an overwhelming proportion of precursors found at illicit methamphetamine sites has involved non-traditional brands sold through convenience stores,'' *id.* at 4, that DEA had retained an expert in retail marketing and statistics who had concluded that sales of pseudoephedrine products at convenience stores in Tennessee and Georgia ''averaged between $15.00 and $60.00 per month'' per store and that sales of combination ephedrine products were even lower, *Id.* at 5, and that ''[c]onvenience store purchases of case quantities of high count/high strength pseudoephedrine products [are] consistent with diversion of the products into the illicit manufacture of methamphetamine.'' *Id.* at 6. The Show Cause Order further alleged that Respondent had continued selling large amounts of pseudoephedrine ''to convenience stores and gas stations,'' notwithstanding that it had been ''put on notice of the potential illegal character of its activities with the issuance of the original Order to Show Cause'' which was served in October 2004. *Id.* ''[B]ecause of the substantial likelihood that [Respondent would] continue to divert listed chemical products,'' I thus concluded that Respondent's ''continued registration, during the pendency of these proceedings, would constitute an immediate danger to the public health and safety.'' *Id.* at 7.[2]

In addition to the above, the Show Cause Order alleged that during a July 2001 inspection, DEA DIs audited Respondent's handling of listed chemical products and determined that it had ''various overages and shortages, including an unexplained shortage of approximately 10,000 bottles of Max Brand, and (another non-traditional brand) *Heads Up* 60 count bottles.'' *Id.* at 5. The Show Cause Order alleged that while inventorying Respondent's listed chemical products, it had ''no traditional brand * * * products but only 'grey market' brands of pseudoephedrine and combination ephedrine products'' which are not sold at drug stores or supermarkets, but ''are typically only sold in locations where goods of these types are not expected to be sold, such as liquor stores, head shops, gas stations, and other small retail stores.'' *Id.*

The Show Cause Order further alleged that following the inspection, DEA DIs conducted verifications of Respondent's customers; the DIs allegedly found that some of the locations were ''non-existent,'' some were residences, and others included such establishments as ''liquor stores, gift shops, a Blimpie restaurant * * * and a magazine store.'' *Id.* Relatedly, the Order alleged that in seeking a registration for its Decatur location, Respondent provided a list of its proposed list I chemical customers which included ''liquor stores, a lotto store, a clothing store, a newsstand, and another distributor.'' *Id.* at 3.

The Show Cause Order also alleged that Respondent would not maintain proper security of listed chemical products at its new proposed location because while its owner, Mr. Shaukat Sayani, had represented that his customers would place their orders ''in person'' and that Respondent would deliver the products by van, the DIs had previously determined that Respondent did not conduct business in this ''manner at [its] Forest Park'' location. *Id.* The Show Cause Order further alleged that Respondent ''intended to co-mingle listed chemical products with

[1] On October 20, 2004, the Deputy Assistant Administrator issued the initial Order to Show Cause to Respondent; the Order proposed the revocation of its registration at its Forest Park location and the denial of its pending application for a registration at its Decatur, Georgia location. ALJ Ex. 1. Each of the allegations of the initial Show Cause Order was repeated verbatim in the subsequent Order to Show Cause and Immediate Suspension of Registration. On November 19, 2004, Respondent, through its counsel, requested a hearing on the allegations of the first Show Cause Order. ALJ Ex. 2.

[2] The Order also alleged that in July 2005, DEA DIs discovered that Respondent ''was also selling one-ounce bottles of liquid iodine to several convenience stores,'' another chemical used in the illicit manufacture of methamphetamine. Show Cause Order at 6. The Order further alleged that ''[i]odine * * * has miniscule sales for use as an antiseptic, even in pharmacies,'' that ''[t]he likelihood of sales of iodine to customers in convenience stores approaches zero,'' and that while Respondent ''sold between 48 and as many as 240 bottles of iodine to individual convenience stores,'' it ''never reported these transactions * * * as extraordinary sales or suspicious transactions.'' *Id.*

non-regulated products on the warehouse floor,'' that it ''had no procedure in place to detect theft or loss at the warehouse,'' that its ''proposed method of sales recordkeeping * * * was inadequate to comply with 21 CFR 1310.06,'' and that it had no means of ''compar[ing] sales between its two * * * locations in order to determine if excessive or suspicious transactions were being encountered.'' *Id.* Relatedly, the Show Cause Order alleged that warehouse security at the Forest Park location was inadequate. *Id.* at 5.

On September 13, 2005, Respondent requested a hearing on the allegations of the Order to Show Cause and Immediate Suspension and moved to consolidate the two proceedings. ALJ Ex. 7. While the hearing on the original Show Cause Order had been scheduled to begin on September 20, 2005, Respondent's counsel sought a continuance to obtain additional time to prepare. Accordingly, the ALJ ordered that the original hearing be cancelled. On December 14, 2005, the ALJ conducted a pre-hearing conference and set the hearing for March 21, 2006. ALJ Decision (ALJ) at 2–3.

Thereafter, on February 27, 2006, Respondent's counsel filed an emergency motion for a continuance. The ALJ granted the motion and subsequently rescheduled the hearing to begin on August 15, 2006. *Id.* at 3.

A hearing was held on August 15 through 18, 2006, at which both parties called witnesses to testify and submitted documentary evidence. At the hearing, Respondent also submitted a motion for summary judgment. *Id.* (citing RX 26). Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On May 4, 2007, the ALJ ordered the parties to file a joint status report regarding Respondent's Forest Park registration. On June 11, 2007, the parties filed the report; the report stated that ''it is the position of the agency and Respondent that [it] currently has a pending application for renewal of its currently suspended registration.'' Joint Status Report at 2.

On August 17, 2007, the ALJ issued her recommended decision. In her decision, the ALJ concluded that Respondent did not maintain effective controls against diversion because it did not ''verify the legitimacy of its customers,'' sold ''suspiciously high quantities of iodine products to some customers'' even though its owner ''was repeatedly made aware of iodine's role as a methamphetamine precursor,'' had ''inadequate inventory procedures [and] poor recordkeeping,'' and failed ''to report suspicious transactions.'' *Id.* at 29–30.

The ALJ also concluded that Respondent was not in compliance with federal law because it ''could not account for large quantities of missing bottles of product,'' and ''did not keep adequate records'' of its sales which ''hindered [its] ability to ascertain whether a customer had purchased an amount above the regulated threshold.'' *Id.* at 31. The ALJ further found that ''Respondent has distributed large, case quantities of pseudoephedrine and ephedrine products,'' as well as ''large amounts of 2% iodine,'' and that ''even [its] witness concurred that some of [its] sales were in excess of what would be expected.'' *Id.* at 32–33. Finally, the ALJ noted that ''[m]any of the 'businesses' to which Respondent sold list I chemical products operated within the * * * non-traditional market for such products,'' that sales to the non-traditional market create an ''unacceptable risk of diversion,'' and that ''[s]ome of [Respondent's customers] did not even appear to be tangentially related to the legitimate sale of pseudoephedrine and ephedrine products.'' *Id.* at 34.

The ALJ did note that Respondent had improved its security and had ''conduct[ed] some investigations into some of its customers' business identities.'' *Id.* at 34. The ALJ concluded, however, that Respondent's ''cooperation is dwarfed by the significant risk of diversion posed [by its] continued sales of listed chemical products to [non-traditional] customers without adequate sales records or customer verification,'' and that it ''has not provided sufficient evidence * * * that its future conduct would change to the degree necessary to eliminate the threat to the public interest.'' *Id.* at 35.

The ALJ further rejected Respondent's arguments that the Government was denying it equal protection of the laws under the Due Process Clause of the Fifth Amendment. More specifically, Respondent argued that it was being held '' 'to a different standard than [the Government's] published rules dictate,' '' *id.* (quoting Resp. Br. at 16), that the Agency had not ''put Respondent on notice as to what specific action would be a violation [of its] rules and regulations,'' *id.* (quoting Resp. Br. at 17), and that ''the agency [was] 'exercising uncontrolled discretion.' '' *Id.* (quoting Resp. Br. at 20).

Finally, the ALJ rejected Respondent's contention that it was entitled to judgment as a matter of law because its sales did not exceed the 1,000 gram monthly threshold (which triggers various reporting and recordkeeping) requirements. *Id.* at 37. Citing several DEA decisions, the ALJ explained that ''Respondent need not exceed the Government's threshold of allowed sales in order to [be deemed to have] act[ed] in a manner inconsistent with the public interest.'' *Id.* (citations omitted).[3]

While the ALJ did not make an express finding that Respondent's continued registration is inconsistent with the public interest, such a finding is implicit in her recommended sanction that Respondent's registration at its Forest Park location should be revoked and its pending application for a registration at its Decatur location should be denied. ALJ at 38. Thereafter, both parties filed exceptions to the ALJ's decision.

The Government's exception noted that while it concurred with the ALJ's recommendation, it was ''not apparent whether the ALJ actually made a finding that Respondent's continued registration would not be in the public interest.'' Gov. Exceptions at 1. The Government thus requested that I ''make a finding that Respondent's continued registration and pending application for registration are not in the public interest as that term is used'' in the applicable provisions of the Controlled Substances Act. *Id.*

The Government also took exception to three of the ALJ's factual findings (FOFs 52, 57, 58), pertaining to the testimony of the Government's expert on the expected sale range of listed chemical products at convenience stores and other non-traditional retailers of these products. *Id.* at 2. More specifically, the Government took exception to the ALJ's findings that Respondent's expert had credibly testified that the Government's expert had made several ''flawed assumptions'' including ''that everybody sells everything in'' the product category, and that as a result, ''the average convenience store might sell $173.25 of list I chemical products per month,'' and that ''this number [is] more credible than the $82 value'' given by the Government's expert.[4] ALJ at 23–24; Gov. Exceptions at 2.

Because ''Respondent sold in excess of both experts' figures,'' the Government declined to ''opine'' as to

[3] The ALJ also noted that there was no evidence that supported Respondent's contention that it is being discriminated against because its owner ''is a legal alien who is attempting to operate a business in this country in accordance with its laws.'' ALJ at 37 (quoting Res. Br. 24).

[4] The ALJ noted, however, that ''even using this larger number * * *. Respondent repeatedly sold list I chemical products in excess of $173.25 per month.'' ALJ at 24.

whose expert's sales figures were ''exactly correct'' or whether ''there is a more precise figure somewhere between their numbers.'' Gov. Exceptions at 2–3. The Government nonetheless urged that I not adopt the ALJ's finding because Respondent's expert's ''analysis of this case was not in detail, but quite limited,'' and the expert ''did not perform his own independent analysis of the data, but only compared end data from two different parts of [the Government expert's] report.'' *Id.* at 3.

In its exceptions, Respondent also noted that the ALJ had not made a finding as to whether its continued registration would be in the public interest and argued that ''no such ruling would be appropriate in this matter.'' Resp. Exceptions at 2. More specifically, Respondent contends that it has ''complied with every request that was given to it by the DEA, repeatedly requested of DEA what they wanted it to do and was willing to do anything the DEA wanted.'' *Id.* at 3. It further contends that the Show Cause Orders were based on Respondent's exceeding sales levels, but that the Government's evidence on the expected sales was ''not credible,'' and that therefore, the Government has not carried its burden of showing that its registration would be inconsistent with the public interest. *Id.* at 4.

Respondent also takes exception to the ALJ's finding that it has ''inadequate inventory procedures.'' *Id.* at 4 (citing ALJ at 30). More specifically, Respondent contends that ''there is no requirement under any of the DEA rules to have an inventory system, and [that it] is once again being asked to comply with something that is not in the DEA rules.'' *Id.* at 5. Respondent thus contends that it is ''being held to [a] previously unspecified and unpublished * * * guideline[ ],'' and that in doing so, the Agency is violating its constitutional rights to due process and equal protection. *Id.* at 5. Finally, Respondent contends that the ALJ ''ignore[d] the substantial remedial actions that [it] had taken to correct problems of which the DEA had notified it.'' *Id.*

Thereafter, the record was forwarded to me for final agency action. Having considered the record as a whole, as well as the exceptions of both parties, I adopt the ALJ findings of fact except as expressly noted herein. I further conclude that the Government has made out a *prima facie* case that Respondent's registration would be inconsistent with the public interest and that Respondent has failed to present sufficient evidence to establish that it will maintain effective controls against diversion in the future. I also reject Respondent's constitutional claims and its motion for judgment as a matter of law. I therefore also adopt the ALJ's recommended sanction that Respondent's Forest Park registration be revoked and its applications for renewal of the latter registration and for a registration at its Decatur location be denied. I make the following findings.

Findings

Respondent is a corporation which engages in the wholesale distribution of assorted products to gas stations, convenience stores, dollar stores, beauty stores, and other establishments. Tr. 701. Respondent is owned by Mr. Sunny Sayani, *id.*, and operates two warehouses which are located in Forest Park and Decatur, Georgia. *Id.* at 702. According to the record, Respondent operates ''a cash and carry'' business in which its customers come to the warehouse to purchase the products they need. RX 25a, Tr. 731.[5]

Respondent currently holds DEA Certificate of Registration, # 004550SLY, which authorizes it to distribute the list I chemicals ephedrine and pseudoephedrine out of its Forest Park warehouse. Tr. 245; GX 1. While Respondent's registration expired on February 28, 2005, it filed a renewal application and paid the requisite fee at some point in January 2005. See Joint Status Report at 1–2. Accordingly, Respondent has a registration, albeit one that has been suspended, at its Forest Park location.

Methamphetamine and the Market for List I Chemicals

Both pseudoephedrine and ephedrine have therapeutic uses and are lawfully marketed as non-prescription (OTC) drug products under the Federal Food, Drug and Cosmetic Act. GX 15, at 3. Pseudoephedrine is approved for marketing as a decongestant; ephedrine (in combination with guaifenesin) is approved for marketing as a bronchodilator.[6] *Id.* at 4. Both pseudoephedrine and ephedrine are, however, regulated as list I chemicals under the Controlled Substances Act because they are precursor chemicals that are easily extracted from OTC 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); GX 15, at 8 (noting that ''the production of methamphetamine from ephedrine or pseudoephedrine can be accomplished via a simple one step reaction and can be accomplished with little or no chemistry expertise'').

Methamphetamine is a highly addictive and abused central-nervous system stimulant. GX 15, at 9. Methamphetamine abuse has destroyed numerous lives and families and ravaged communities. *Id.*; *see also Rick's Picks, L.L.C.*, 72 FR 18275, 18276 (2007). Moreover, because of the toxic nature of the chemicals used to make the drug, its illicit manufacture causes serious environmental harms. *Id.*; GX 14, at 10.

A DEA Special Agent from the Atlanta Field Division testified regarding the rapid growth of illicit manufacturing of methamphetamine during his tenure in Atlanta. Tr. 29. According to the S/A's testimony, over ''a short period of time'' the number of meth. lab seizures by DEA and local law enforcement had ''multiplied by ten times.'' *Id.* Other evidence showed that between 1999 and 2004, the number of seizures in the State of Georgia had increased from 34 to 229.[7] *See* GXs 9 & 35.

The Special Agent, who had debriefed over 200 individuals involved in the illicit manufacture of methamphetamine, Tr. 39, also testified that convenience stores, gas stations, and other small retailers were the primary source of the ephedrine and pseudoephedrine which was used by ''mom-and-pop'' meth. labs. *Id.* at 56 & 59. The Agent further testified that meth. cooks use individuals known as ''runners'' who would travel to different stores and purchase small amounts each day to avoid detection. *Id.* at 62. Moreover, runners generally avoided larger retailers such as chain stores because these establishments have ''too much security'' and ''too much video surveillance,'' *id.* at 56, and have ''been very militant on * * * limit[ing] sales'' of the drugs. *Id.* at 102; *see also id.* at 100.

The S/A also testified that in some instances, meth. cooks recruited multiple persons to go to smaller stores and buy the maximum amount of product the store would sell them. *Id.* at 63. Moreover, in some instances, either the owner or an employee of a smaller

[5] Respondent's owner testified that it delivers, but that the customer must ''buy more than $1000'' to justify the expenses of paying for the driver, gasoline and the truck. Tr. 731.

[6] In July 2005, the Food and Drug Administration issued a notice of proposed rulemaking which proposes to remove combination ephedrine/guaifenesin products from the OTC monograph on the ground that these drugs are not safe and effective for OTC use. 70 FR 40232 (2005).

[7] Between 1999 and 2004, the States adjacent to Georgia also experienced large increases in the number of meth. lab seizures. In Alabama, the number of seizures increased from 27 to 369; in Tennessee, the number increased from 106 to 1251; and in South Carolina, the number increased from 5 to 153. *See* GXs 9 & 35.

store would sell a case quantity of a listed chemical product to a person affiliated with a lab. *Id.*

The Government also established that the overwhelming majority of commerce in non-prescription drug products occurs in drug stores, supermarkets, large discount merchandisers and electronic shopping/mail order houses. GX 25. According to the declaration of Jonathan Robbin,[8] who has testified in numerous DEA and federal court proceedings as an expert witness on the market for list I chemical products containing pseudoephedrine and ephedrine, ''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.'' *Id.* at 4; *see also* GX 24, at 3.[9] According to Mr. Robbin, these retailers ''constitute the traditional marketplace where [nonprescription drugs for coughs, cold, nasal congestion, and asthma] are purchased by ordinary consumers.'' GX 25, at 4.

Mr. Robbin has further concluded that sales of non-prescription drugs at convenience stores ''account for only 2.2% of the overall sales of all convenience stores that handle the line.'' *Id.* Moreover, only 4.87% of convenience store shoppers purchase a non-prescription drug product, GX 24, at 5; and only 4.59% of these shoppers purchase a pseudoephedrine product.[10] *Id.* at 4. Mr. Robbin thus concluded that .21% of convenience store shoppers purchased a pseudoephedrine product. *Id.* at 5. In another document, Mr. Robbin explained that by extrapolating data from the 1997 U.S. Economic Census data and information obtained from surveys of the National Association of Convenience Stores, he had estimated that during 2005, ''[t]he expected average monthly convenience store sales of nonprescription drug products containing pseudoephedrine (hcl) in Georgia were * * * $82.'' GX 26 at 2.[11]

Respondent called as an expert witness, Dr. Danny N. Bellenger. Dr. Bellenger holds a PhD in Business Administration and is a Professor and Marketing Research Fellow at the Robinson College of Business at Georgia State University. RX 31, at 2. Dr. Bellenger previously served as chairman of the Department of Marketing at Robinson, and was the Dean of the College of Business at Auburn University. *Id.*

Dr. Bellenger disputed Mr. Robbin's figures for the expected monthly sales range of pseudoephedrine at convenience stores. Dr. Bellenger testified that he did not agree with the conclusions of Mr. Robbin's reports and that reports did not ''agree with each other.'' Tr. 521. More specifically, Dr. Bellenger noted that one of Mr. Robbin's reports stated that ''two in 1,000 * * * convenience store shoppers would be expected to buy Sudafed,'' but in another report, Mr. Robbin had stated ''that there's 120,000 purchasers or customers [who] come into a convenience store.'' *Id.* at 523; *see also* GX 25, at 11 (stating that ''[t]he average annual number of shoppers in a convenience store (excluding gasoline purchases) is about 120,000'').[12]

Dr. Bellenger explained that if two out of a 1,000 customers purchased pseudoephedrine and a convenience store has 120,000 customers, at least 240 of these persons would buy the product over the course of a year or ''twenty per month for an average convenience store.'' Tr. 523. Dr. Bellenger testified that multiplying this number ''times the average retail price of * * * Sudafed'' gives an ''estimate of about $170 * * * based on the numbers that are in the reports.'' *Id.*

Dr. Bellenger subsequently testified that he determined the average price of Sudafed by ''looking at the wholesale prices and assuming a markup,'' and that he ''also looked in Kroger to see what it cost, but [the price] would vary a lot * * * by store.'' *Id.* at 662–63. However, Dr. Bellenger did not ''recall the actual figure'' he used for the retail price. *Id.* at 663. Nor did he explain what source he used for the wholesale price figure, or what price he used.

Dr. Bellenger also testified that he confirmed his estimate by multiplying the percentage of convenience store shoppers who purchase pseudoephedrine (.0027) times the average annual merchandise sales of convenience stores ($770,000). Dividing this figure by twelve results in a monthly sales figure of $173.25, which is ''a similar number'' to the sales figure obtained in the first method. *Id.* at 524.[13]

Dr. Bellenger further testified that Mr. Robbin's methodology was based on several assumptions which he contended ''are not consistent with reality.'' *Id.* at 527. More specifically, he contended that one of Mr. Robbin's assumptions was that ''all retailers [including] convenience stores carry a full line of all'' non-prescription medicinal products that are reported in the Economic Census's merchandise line, and that this is ''not consistent with the common practice'' because ''a convenience store * * * carries a much narrower line of most products.'' *Id.* at 526; *see also id.* at 583, 664. According to Dr. Bellenger, ''when the conveniences stores sell less than a full line and the supermarkets and drugstores sell the full line, * * * it distorts the numbers,'' by ''caus[ing] the estimate for Sudafed for the convenience store to be lower than it actually should be.'' *Id.* at 664.[14]

While the ALJ credited Dr. Bellenger's testimony that the monthly expected sales figure of pseudoephedrine products at convenience stores was $173.25, *see* ALJ at 24, I decline to adopt this finding. While Dr. Bellenger's testimony that approximately 240

[8] Mr. Robbin holds degrees from Harvard College and Columbia University and is an expert in multivariate statistical analysis and the processing of economic census and population data. *See* GX 25, at 1–2. He also founded Claritas, Inc., a company which is now the largest producer and seller of census-based consumer marketing information products, systems and services. *Id.* at 1.

[9] According to this report, convenience stores selling gasoline account for 1.75% of the non-prescription drug market; convenience stores that do not sell gasoline account for .95% of the market. GX 24, at 3. All other establishments combined account for only .21%. *Id.*

[10] While the text accompanying table 3 uses the figure of 5.59% as the percentage of non-prescription drug buyers who purchase pseudoephedrine at convenience stores, the previous table makes clear that the actual percent is 4.59%. *Compare* GX 24, at 5, with *id.* at 4.

[11] Mr. Robbin noted that data from the 2002 Economic Census for Florida (a neighboring State) indicated that the expected sales were 21% lower than the data from the 1997 Economic Census suggested. GX 26, at 1–2. Mr. Robbin thus stated that ''using the same factor as encountered in Florida would produce an updated estimate of $65.'' *Id.* at 2.

[12] With respect to the number of convenience store shoppers who would purchase Sudafed, Dr. Bellenger testified that ''[t]he numbers which I've computed actually says its 2.7 [out of 1,000], but * * * that's a relatively minor difference.'' Tr. 523. Dr. Bellenger testified that he used ''the data that was in [Mr. Robbin's] report, and [did] exactly the computations [Mr. Robbin] did * * * and came out with * * * 2.7 customers in 1,000.'' *Id.* at 581. In his testimony, Dr. Bellenger did not specifically identify which figures he used, and as explained above, it appears that one of Mr. Robbins' reports contains a transcription error. *See supra* n. 10.

[13] Notably, Dr. Bellenger used the figure which appears to be based on a transcription error in one of Mr. Robbin's reports. If, however, the .0021 (or 2.1 shoppers out of 1,000) figure is used, *see* GX 24, at 5; the average monthly sale is $134.75.

[14] Dr. Bellenger also testified that one of Mr. Robbin's reports assumed that all stores were ''expected to sell the same amount,'' and that this requires the assumption that the stores are ''all the same size'' and ignores the stores' locations. Tr. 529. As Dr. Bellenger further testified, ''[i]f you've got a very large store attached to a gasoline station selling on the interstate, the mix of products is not going to be the same as a small rural store.'' *Id.* at 530. I note, however, that in one of the reports, Mr. Robbin estimated a sales range which was based on ''differences in sales occurring as a consequence of store size, location, hours, advertising expenditures and management practices.'' GX 25, at 7. This would appear to address Dr. Bellenger's testimony on this point.

persons would purchase pseudoephedrine at a convenience store over the course of a year calls into question the validity of the Government's figure, he did not establish the source of the wholesale price information (and the price) that he relied upon or the amount of markup he used. As for his testimony regarding pricing at Kroger, he did not testify as to what that price was, what size package it was, and stated that the price would vary a lot by store. Finally, while Dr. Bellenger ''confirmed'' his estimate by multiplying the percentage of convenience store shoppers who purchase pseudoephedrine by the average store's sales volume, this methodology seems to require a major assumption in its own right—that the average amount spent by a customer in purchasing pseudoephedrine is the same as the average purchase of those convenience store customers who buy other products.

Accordingly, I conclude that neither the Government's nor Respondent's evidence reliably establishes the monthly expected sales range.[15] For purposes of this case, I assume without deciding that Dr. Bellenger's figures are accurate.

Dr. Bellenger also testified regarding several other matters. With respect to the size of a retailer's purchases, Dr. Bellenger testified that buying a case quantity may be a legitimate business decision ''to invest in more inventory so as to lower [its labor] cost of taking inventory and processing order forms.'' Tr. 549. According to Dr. Bellenger:

> The simple fact that someone, in * * * their business model, decides to order in large quantities is not necessarily suspicious in and of itself. What would be suspicious to me is if someone repeatedly ordered in large quantities. So I would think that looking for repeated large quantity orders by the same store or a combination of products which go into the production and ordering in large quantities * * * of a group of products which are involved in the manufacture of some illicit substance would be important for determining suspicious orders.

Id. at 549–50.

Amplifying this testimony, Dr. Bellenger added that to purchase a case quantity (144 bottles) is ''one of two things. It's a conscious business decision where a store owner has decided it's more efficient to order in large quantities, put it in the stockroom, and make fewer orders, and have less labor involved.'' *Id.* at 570. Dr. Bellenger than allowed that ''maybe there's some nefarious practice involved here,'' but that if this was so, ''you would see repeat purchases of large quantities.'' [16] *Id.* at 570–71.

The ALJ also credited Dr. Bellenger's testimony that in reviewing the various exhibits, he noted that while ''some of [Respondent's customers] were buying by case lot,'' he did not find a pattern of the customers ''buying [ten] 144s.'' Tr. 571 (cited at ALJ at 25). Respondent's own evidence shows, however, that there were multiple instances in which Respondent sold case quantities that suggest that the sales were for an illicit purpose. *See* RX 12.

For example, during the year 2004, Respondent sold cases (144 bottles) of Max Brand Pseudo to the Coastal Food Mart of Rockmart, Georgia, on eight occasions: January 21, February 2, March 4, April 19, June 3, July 14, August 2, and September 5.[17] *Id.* at 52, 82, 86, 91, 93, 97, 99. On cross-examination, Dr. Bellenger acknowledged that the store was ''probably * * * buying in excess of what would be expected,'' that ''a case over a six-month period is rational,'' but this store's purchases ''would raise [his] suspicions.'' Tr. 619–20. Moreover, when asked whether this store's retail sales would be ''many standard distributions beyond'' the $175 figure he calculated for average monthly sales, Dr. Bellenger answered: ''Right.'' *Id.* at 620. Dr. Bellenger also acknowledged that it would not be logical for a store to ''order additional inventory on a regular basis unless they were selling it.'' *Id.* at 642.

On re-direct, Dr. Bellenger opined that ''it would be highly unlikely in the normal course of business'' for an entity like Sunny Wholesale to detect these transactions. *Id.* at 646. According to Dr. Bellenger, ''you've got to be looking real, real, real close'' to find these transactions ''given the scope of [Respondent's] business,'' and the fact that the product category was ''less than two percent of the total business and these instances would account for a fraction of that.'' *Id.* at 647.

The Coastal Food Mart was not, however, the only store to which Respondent repeatedly sold large quantities of pseudoephedrine. During the same year, it sold a case quantity to Chitra Inc.'s Quick Stop of Rome, Georgia, on eight separate dates: January 4, April 8, June 14, July 5, August 2, August 20, September 14, and October 11. *See* RX 12, at 80, 91, 94, 95, 97, 98, 100, & 101. It sold a case to the Phillips 66 Mart of Hapeville on eight occasions: January 5, February 5, March 22, April 1, May 5, June 3, August 17, and September 12. *See id.* at 80, 84, 88, 89, 92, 93, 98 & 99.

It sold a case to the R & S Grocery of Columbus on nine dates: January 21, February 2, March 2, April 1, May 5, June 21, July 7, August 30, and September 29. *See id.* at 82, 86, 89, 92, 95, 96, 98, & 100. It sold a case to the Stop In of Bremen on nine occasions: January 5, February 3, March 2, April 1, May 5, June 1, July 27, August 20, and September 14. *See id.* at 52, 80, 83, 86, 89, 92, 93, 98, 100.

Moreover, the record shows that there were instances in which Respondent sold to two customers who used the same address. For example, Respondent sold case quantities to the P & K Mini Mart, with an address of 461 Columbia Drive, Carrollton, on January 6, February 10, March 4, April 8, and May 5. *See id.* at 53, 81, 84, 86, 89. Yet it also sold a case to a customer it listed as the ''Quick Stop/Tushar/BP'' with the same 461 Columbia Drive, Carrollton address, on February 2, March 4, April 8,[18] May 5, July 22, and August 1. *See id.* at 54, 83, 86, 91, 96, 97. Moreover, Respondent sold a case to the DJ Food Mart, with an address of 15582 HWY 27, Trion, on January 6, February 10, March 4, April 8, May 5, and June 15. *See id.* at 54, 81, 85, 87, 90, 94. It also sold a case to a customer it listed as ''BJ's Food Market # 1'' with the address of 15582 HWY 27 North, Trion, on February 10, March 4, April 8, May 5, June 4, July 27, July 22, August 18, and September 5. *See id.* at 54, 84, 87, 90, 93, 96, 98, 99.

Relatedly, Dr. Bellenger testified that ''unusual orders become very challenging if there's a relatively small number of * * * those orders * * * given the large numbers of people [a business is] dealing with.'' *Id.* at 556. Dr. Bellenger acknowledged, however, that ''you could create a computer program which would create an exceptions report.'' *Id.* at 648. Dr. Bellenger nonetheless maintained that it would be difficult to track these

[15] Accordingly, I agree with the Government's exception and decline to adopt the ALJ's finding.

[16] Dr. Bellenger added that he was not ''sure how much of this is stuff is required to make the illicit drugs in question,'' and that he was ''not sure if 144 [bottles] will make enough to matter or not.'' *Id.* at 571. The Government's evidence showed, however, that Georgia and the adjacent States had experienced a proliferation in smaller methamphetamine labs which typically produced a quarter to a half ounce. *Id.* at 35. The evidence also showed that ''even unskilled persons can obtain a 50–70% yield of methamphetamine.'' GX 15, at 8. Contrary to Dr. Bellenger's understanding, four sixty-count bottles of 60 mg. pseudoephedrine would provide enough material for even an unskilled person to manufacture a quarter ounce of the drug; 144 bottles would provide enough material to make nine ounces.

[17] Each case sold for $1006.56.

[18] The record indicates that on this date, Respondent sold 96 bottles for a total sale of $671.04. RX 12, at 91.

purchases and that finding a high volume purchase ''in the normal course of business would be an accident.'' *Id.* at 647.

I reject Dr. Bellenger's testimony regarding the difficulty of detecting excessive purchases. As noted below, during an earlier meeting with DEA investigators, Mr. Sayani stated that ''a typical sale'' of listed] chemicals ''was two to three boxes,'' with each ''box contain[ing] twelve bottles of 60-count tablets.'' *Id.* at 331. Notably, during this meeting, the DI specifically told Mr. Sayani that an order of ''ten boxes [or 120 bottles] would be suspicious,'' and that if a customer ''requested cases quantities'' or 144 bottles, ''he was to notify DEA.'' *Id.* at 336.

Moreover, Respondent's records show that many of these customers were not trying to hide the size of their purchases by purchasing smaller quantities on different dates. Rather, they were openly ordering case quantities, *see* RX 12, at 79–101; and as found above, several of these customers did so with disturbing frequency. Finally, even crediting Dr. Bellenger's testimony that in some instances, a convenience store owner could make a legitimate business decision to purchase a case quantity, it does not require that much effort to call up a customer's account history to determine how frequently the customer was purchasing the products.

Respondent's History as a Registrant

In September 1999, Respondent applied for a DEA registration to handle list I chemicals at its Forest Park warehouse. Tr. 703. Prior to being granted the registration, DEA DIs conducted a pre-registration inspection. *Id.*; *see also id.* at 323. During the inspection, a DI provided Mr. Sayani with a copy of the DEA *Chemical Handler's Manual* and a document which listed the thresholds for pseudoephedrine and ephedrine (which trigger additional reporting and recordkeeping obligations). *Id.* at 726–27. Moreover, Mr. Sayani told the DI that ''he would deliver [the listed chemical products] to his customers.'' *Id.* at 323.[19] Shortly after the inspection, Respondent obtained a registration for this location.

On January 31, 2001, Respondent applied for a registration to handle pseudoephedrine, ephedrine, and phenylpropanolamine, at its Decatur warehouse. GX 2. Accordingly, on March 31, 2001, DEA DIs went to Respondent's Decatur facility to conduct a pre-registration inspection. Tr. 246. During the inspection, the DIs met with Mr. Sayani and provided him with another copy of the *Chemical Handler's Manual*, as well as notices stating that drug products containing phenylpropanolamine were being used by drug traffickers to manufacture amphetamine, GX 5, and combination ephedrine and pseudoephedrine were being used to by traffickers to manufacture amphetamine and methamphetamine. GX 6, Tr. 249. The DIs also provided Mr. Sayani with notices pertaining to recordkeeping and reporting of theft and losses of listed chemical products. Tr. 249.

The DI had previously requested that Mr. Sayani provide her with lists of his suppliers, the products he intended to carry, and his proposed customers. *Id.* 246–47. On the list of suppliers and products, Mr. Sayani indicated that he intended to sell products distributed by Compare Generics of Hauppauge, New York, including Max Brand and Heads Up, two brands of products which ''are notoriously popular [with] methamphetamine traffickers.'' [20] GX 34, at 11; GX 27.

During the inspection, the DIs reviewed the *Chemical Handler's Manual* with Mr. Sayani, placing special emphasis on its provisions pertinent to record keeping, security, the need to know his customers, and requiring proof of identity from his customers. Tr. 321. The DIs also discussed with Mr. Sayani the listed chemical thresholds and the requirement to report suspicious orders. *Id.* Mr. Sayani again represented that the listed chemical products ''would be delivered just like they were at his Forest Park location.'' *Id.* at 323. The DI observed, however, that Respondent did not ''deliver most of the time'' as ''[t]he majority of the time the customers were coming'' to the warehouse. *Id.* at 324.[21]

Based on Mr. Sayani's list of proposed customers, one of the DIs checked to see if DEA's computer system held information regarding the customers. *Id.* at 255. The DI also visited several of the customers' addresses to verify whether there was a business at the location. *Id.*

Moreover, the DIs' supervisor decided that before sending the report on the Decatur application to DEA Headquarters, the DIs needed to inspect Respondent's practices at its Forest Park warehouse because the location had ''never been audited.'' *Id.* at 370. Accordingly, on June 30, 2001, several DIs went to the Forest Park warehouse and conducted an inspection. *Id.* at 255.

Upon their arrival, the DIs met with Mr. Sayani and asked him to provide them with an inventory and a list of the listed chemical products Respondent distributed. *Id.* at 256. One of the DIs also asked him for a list of his customers and suppliers and provided him with another copy of the *Chemical Handler's Manual* and several DEA notices. *Id.* During the inspection, the DIs observed that Respondent's list I products were co-mingled with other products in the warehouse and were not stored in a secure area.[22]

The DIs then proceeded to conduct an audit of Respondent's handling of list I products for the period January 1, 2001, through the close of business on June 30, 2001. GX 31. The DIs selected eleven non-traditional products to audit; with the assistance of Mr. Sayani, they counted the actual number on hand of each of the selected products. Tr. 264 & 275; GX 30.[23] Because Mr. Sayani did not have a previous inventory of the products,[24] *id.* at 260, the DIs assigned an opening value of zero for each of the products. *Id.* at 377; GX 31. Assigning an opening value of zero for a product should result in an overage if, in fact, there was any of the product on hand on the beginning date of the audit and the distributor is keeping (and provides) complete records of its purchases and distributions.[25] Tr. 269 & 377.

To complete the audit, the DIs requested that Mr. Sayani provide them with his purchase invoices and sales invoices. *Id.* at 266. The sales invoices did not, however, clearly indicate the package size (e.g., whether it was a six count packet or 60 count bottle). *Id.* at

[19] Mr. Sayani made the same representation during the pre-registration investigation of Respondent's application for the Decatur location. Tr. 323.

[20] On its product list, Respondent also indicated that he would be distributing four products from BDI Marketing, Inc., another firm whose products have been found at numerous illicit methamphetamine labs. GX 4. However, according to the DI, none of these products contained a list I chemical. Tr. 250.

Respondent also listed three other suppliers; the listed chemical products he listed under these suppliers were nationally recognized brands such as Tylenol, Advil, Nyquil, Contac, and Vicks 44. *See* GX 27.

[21] The DI also obtained information that Respondent had a single employee who was ''his delivery guy.'' Tr. 324. The position was vacant for some unspecified period of time. *Id.* at 324–25.

[22] At some point between 2002 and 2005, Respondent built a cage at its Forest Park warehouse in which it stored its list I chemical products and installed several security cameras. RX 25a. The cage had a separate cash register and window at which the products were paid for and delivered to the customer. *Id.*

[23] The DIs provided Mr. Sayani with a copy of the count. Tr. 362.

[24] At the hearing, a DI testified that DEA's regulations do not require that a list I chemical distributor keep an inventory. *Id.* at 261.

[25] Assigning an opening value of zero will also result in an undercount of a shortage if any product had actually been on hand on the opening date of the audit.

267. The DI therefore contacted Mr. Sayani and requested additional information. *Id.* at 266–67. While Mr. Sayani then provided his sales tracking reports, even these were sometimes lacking the necessary information. *Id.* at 267.

The audit found that there were shortages with respect to six of the eleven products.[26] *See* GX 31. Most significantly, Respondent was short 7640 sixty-count bottles of Heads Up and 3656 sixty-count bottles of Max Brand. *Id.* Moreover, Respondent was short 284 sixty-count bottles of Mini 2-Way Action. *Id.* Respondent was also short 180 six-count packets of Max Brand, 154 six-count packets of Mini 2-Way Action, and 262 packets of Max Brand Pseudo (24-count). *Id.*

Regarding the audit, Mr. Sayani testified that upon being served with the Show Cause Order, which had alleged that he was short approximately 10,000 bottles of Max Brand and Heads Up, he checked his July 2001 inventory and had 2069 bottles on hand and did not ''know where this 10,000 figure came from.'' Tr. 715. Mr. Sayani further testified that because 10,000 bottles is a large amount, he ''would know where [it] is going.'' *Id.* at 716.

The ALJ did not make ''precise findings'' on the amount of the shortages. ALJ Dec. 30 at n.6. I do.

Notably, Mr. Sayani's testimony that he had 2069 bottles on hand according to his July 2001 inventory is consistent with the total amount of product that he and the DIs physically counted.[27] Moreover, the DIs found that the largest shortage was in the Heads Up 60-count bottles, yet none of this product was on hand when the physical count was on hand. *See* GX 31. The audit of this product was thus based entirely on Respondent's records of its purchases and distributions; if the amount was incorrect, Respondent could have produced his records to show that.

Moreover, for each of the audited products, the amount of the shortages (11,296 60-count bottles of Max Brand and Heads Up) was determined based on the discrepancy between the amount of these products which Respondent obtained from his suppliers during the audit period and the sum of the amount it had on hand on June 30 and the amount its sales records showed it had distributed during the audit period. Mr. Sayani's assertion aside, he offered no credible evidence that gives me reason to reject the audit's finding. Accordingly, I adopt as findings, the audit results as listed in GX 31.

As found above, during the visit, the DIs also discussed with Mr. Sayani the size of a normal monthly sale to a single store of non-traditional products. *Id.* at 330. Mr. Sayani told the DIs that ''[a] typical sale was two to three boxes,'' with each ''box contain[ing] twelve bottles of 60-count tablets.'' *Id.* at 331. As found above, however, Respondent frequently sold listed chemical products in far larger quantities and did so notwithstanding that the DIs had informed him that sales of case quantities were suspicious and should be reported to DEA. *See* RX 12; Tr. 336.

Following the inspection, several DIs were assigned to conduct customer verifications.[28] ALJ at 15–17. The verifications serve several purposes including determining whether the customer actually exists, the nature of its business and whether it is legitimate, and whether the customer has a business relationship with the distributor. Tr. 139, 145, 187, 202, 355–56. As the ALJ found, the verifications produced ''mixed results.'' ALJ at 15.

One DI, who was assigned twelve verifications, found that several of the businesses were convenience stores, gas stations, and a liquor store. Tr. 142–45. Moreover, upon visiting the addresses of three of the customers, two of which were listed as businesses (Pamela's Unique Clothing and Reliance Wholesale Supply), and one which was listed as an individual (M.S.), the DI found that they were residences and that there were no signs of businesses. Tr. 142 & 144. The DI further found that the R.S. Corporation was a Blimpie restaurant, *id.* at 142, and that Artistic Sales was a gift shop which did not sell list I chemicals. *Id.* at 143.

Another DI testified that when she and her partner went looking for Ashley's Boutique, they could neither find the store nor the address that Mr. Sayani had given for it. *Id.* at 202–03, 233. The DIs further found that the Atlanta Cleaners Plus ''was closed down.'' *Id.* at 203. While the DIs found that the Matierra Mexicana #3 was a supermarket, the store did not purchase items from Respondent. *Id.* at 203–04. Moreover, one of the establishments was a liquor and check cashing store. *Id.* at 204.

Another customer (BDI Inc.) was a Shell gas station whose manager stated that while he had purchased products from Respondent nine months earlier, he no longer did so. *Id.* at 205. Moreover, the manager told the DIs that Respondent ''did not deliver'' and that ''he had to drive to [Respondent's] facility to pick up his products.'' *Id.* Finally, the DIs determined that another customer (Golden Dealers) ''was a house that was located in a cul-de-sac'' and there was no store on the premises. *Id.* at 206.

Following the customer verifications, one of the DIs and her supervisor met with Mr. Sayani and his attorney Henry D. Frantz, Esq., to discuss their concerns that some of Respondent's customers were not legitimate. *Id.* at 254. More specifically, the DI told Mr. Sayani that the DI had ''found numerous suspect customers that normally would not be selling these type of products.'' *Id.* at 372. The DI also expressed her concern that some of Respondent's customers were engaged in wholesale distribution out of their homes and were therefore required to be registered under 21 U.S.C. § 823(h), but were not. *Id.* at 259.

Upon being informed by the DIs that ''some of the customers were suspicious,'' Mr. Sayani stated that he had ''provided * * * a list of the customers he thought * * * would purchase from him, whether it was list I chemicals or other products that he handled.'' *Id.* at 254. At the meeting, the DIs also provided Mr. Sayani and his attorney with a list of 147 customers who they deemed suspicious and instructed him to investigate them. *Id.* at 687.

Several weeks thereafter, Respondent's attorney wrote a letter to the DIs reporting that 119 of the customers owned either a convenience store or grocery. RX 8, at 1. Respondent's attorney further reported that 14 of the customers had ''never purchased a list I'' product and that three of them ''have a DEA license.'' *Id.* As for the remaining suspicious customers, the letter stated that Respondent could not contact eight of the customers and that three of them were jobbers who had purchased small amounts. *Id.*

Respondent's attorney further wrote that it ''had tightened up * * * his business with regard to checking out the customer on all sales pertaining to list I chemicals.'' *Id.* More specifically, the letter stated Respondent ''currently asks

[26] As the DI explained, the audit was conducted by adding Respondent's purchases to the opening inventory figure and comparing that figure with the total of the ending inventory plus the amounts which Respondent distributed to its customers. Tr. 268, GX 31.

[27] Mr. Sayani did not state which products were included in his 2069 figure. According to GX 31, the physical count found 1584 Max Brand (60 count) bottles, 36 Mini 2-Way (48-count) and 428 (60-count) bottles, and 18 Mini Twins (60 count bottles). These products would total 2066 bottles. I further note the testimony that Mr. Sayani agreed with the results of the inventory. Tr. 266.

[28] According to the record, Mr. Sayani provided two separate customer lists. One was a list which Mr. Sayani represented as being his actual Forest Park warehouse list I customers; the other was a list of his potential list I customers for his Decatur warehouse. Tr. 373–74.

for a tax identification number, business license[,] as well as a DEA permit if the customer does not have a store.'' *Id.* at 2.[29]

At the hearing, Mr. Sayani testified that he did not go to a new customer's store to verify whether it was legitimate ''because at the time of opening the account, we get enough proof from them that they're legitimate * * * or that they're who they say'' they are. Tr. 768. Mr. Sayani acknowledged, however, that anyone who applied for a state or local tax identification number would be issued one. *Id.* at 769.

At the hearing, Mr. Sayani further testified that upon being served with the Show Cause Order, which referred to Max Brand and Heads Up as non-traditional products, he stopped selling the products. *Id.* at 714. As found above, the first Show Cause Order was dated October 20, 2004, and served on Respondent no later than November 19, 2004, when his counsel requested a hearing.

Contrary to Mr. Sayani's testimony, Respondent's ''Sales Tracking Report'' indicates that it repeatedly sold Max Brand after the first Show Cause Order was served and frequently did so in large quantities. Moreover, there is evidence that it made multiple large sales to several stores.

For example, on November 30, 2004, it sold $504 of Max Brand 2–Way to the Lucky Star of Brookfield, Georgia. RX 12, at 67. This was followed by two December 12, 2004 sales, each totaling $1509.84, to the Dixie Stop of Twion and the Modern Kwik Shop of Summerville, *id.* at 101, and a December 19, 2004 sale of $504 to Jay Swaminarayan, Inc., of Tifton, Georgia. *Id.* at 74. On February 13, 2005, it sold an additional $861.12 of the products to both the Dixie Stop and the Modern Kwik Shop.[30] *Id.* at 104.

On both November 29, 2004, and January 3, 2005, it sold $1006.56 of the products to ABJ Ashburn, Inc., of Ashburn. *Id.* at 106 & 101. Respondent made further sales of the products to this store on January 27, February 17, and February 25, when it sold $430.56 worth on each date, and on both March 20 and April 2, when it sold $861.12 of the products to this store. *Id.* at 101–2, 105–6.

Moreover, on January 8, 2005, it sold $861.12 of Max Brand pseudoephedrine to Priya Nidhi, Inc., of Calhoun, Georgia. *Id.* at 53. Notably, it has previously sold this establishment $1006.56 on October 15, 2004. *Id.* at 52.

On February 5, 2005, it made two separate sales of the products (one totaling $504, the other totaling $430.56) to the West Gray BP of Gray, Georgia, *id.* at 78 & 112; on February 18, 2005, it sold $504 of the product to the Razk, Inc., Marathon of Douglasville. *Id.* at 64. And on February 20, 2005, it made two separate sales (one worth $504, and one worth $430.56 of the products) to Krishna Corp. of Huntsville, Alabama. *Id.* at 72 & 107.

On January 13, February 6, March 1, and April 1, 2005, it sold $430.56 worth of the products to the Texaco 10 Opelika of Phenix City, Alabama; on January 13, it also sold an additional $576 of the products to this store. *Id.* at 102, 104–06, 113. Moreover, on both February 20 and April 2, it sold $861.12 of the products to USA Trading Inc., of Pheonex (sic) City, Alabama. *Id.* at 102 & 104. It also sold $861.12 of the products to Thakurs Fuel, Inc., of Pinehurst, Georgia, on each of these dates: February 25, March 20, and April 8, 2005. *Id.* at 103, 105 & 109.

The evidence further shows numerous other instances in which Respondent sold large quantities of Max Brand as late as April 2005. *Id.* at 110–12. More specifically, on April 3, 2005, Respondent sold $861.12 of the product to each of the following stores: Amin Enterprises, Inc. of Lithonia, the Coastal Food Mart of Rockmart, and the Hill Top Gas Station of Bremen. *Id.* at 110–11. Moreover, on April 6, it sold $861.12 worth of the products to Wendel's JKF, Inc., Discount Tobacco #2, and Discount Tobacco; all three stores were located in Americus, Georgia.[31] *Id.* at 111. Finally, between April 10 and 16, 2005, it sold $504 worth of the products to eleven establishments (the DM Cotton Patch of Richland, DM Shopper Stop # 334 of Cusetta, OM Traders #271, DM Shopper Stops #s 442 and 451, all of Cataula; KDC Inv. and RDSP, both of Columbus; Hyaat Groceries of Covington; Jai Bhrahmani, Inc., of Buchanan; Gainesville BP of Gainesville; all in Georgia, and Prem, Inc., of Alexander City, Alabama. *Id.* at 111–12.

The ALJ specifically found—based on Mr. Sayani's testimony—that ''Respondent stopped selling Heads Up and Max Brand products because they were identified as 'non-traditional' items by the DEA in the October 2004 Order to Show Cause.'' ALJ at 21. To the extent this finding implies that Mr. Sayani stopped selling the products shortly after service of the Order, it is inconsistent with the evidence which shows that for approximately five months after the Order was served, Respondent continued to sell these products. Indeed, Mr. Sayani's testimony begs the question of why, if the products were identified in the Show Cause Order, it took five months to stop selling them.

The Government also produced evidence showing that Respondent had distributed iodine tincture to several of its customers. *See* GX 46, at 1, 2, 3, 15, & 16. Moreover, Respondent's evidence shows that it distributed 2,852 (1 oz.) units of this product to a single store between June 8, 2003, and November 6, 2004. RX 16, at 5.

Regarding the allegation that Respondent sold excessive quantities of iodine to convenience stores, the Government offered anecdotal evidence in the form of a DI's testimony that she had visited more than 100 convenience stores in both the course of her official duties and as a consumer and had never been able to find tincture of iodine. Tr. 396. But in contrast to the extensive evidence the Government introduced regarding the expected sales range of pseudoephedrine and ephedrine at convenience stores, it produced no such evidence with respect to iodine tincture.

The Government also introduced into evidence several documents indicating that iodine was used in manufacturing methamphetamine. The first of these was a blue notice, which was reprinted in the *Chemical Handler's Manual*, a copy of which was provided to Mr. Sayani at both the pre-registration inspection and the schedule regulatory inspection. Tr. 307. The notice stated that ''iodine became a federally regulated List II chemical on 10/3/96,'' and that it was being provided to ''[m]ake you aware that iodine is being used to clandestinely produce methamphetamine.'' GX 36a.

The Government also introduced into evidence an ''Information Brief'' published by the National Drug Intelligence Center entitled: *Iodine in Methamphetamine Production*. GX 36B; Tr. 308. The document stated that ''[s]mall-scale methamphetamine producers who are unable to obtain iodine crystals occasionally produce them from iodine tincture by mixing iodine tincture with hydrogen peroxide.'' GX 36B, at 2. This document further explained that ''[t]his is a time-consuming process that yields a very small amount of iodine crystals in relation to the amount of tincture and hydrogen peroxide use,'' and also noted that ''[i]odine tincture is not regulated

[29] The letter also stated that Respondent would ''cross-check * * * all customers purchasing list I items between'' its two warehouses, and that it was maintaining ''an updated inventory.'' RX 8, at 2.

[30] Respondent had also sold $1509.84 of the products to the Modern Kwik Stop on November 14, 2004. RX 12, at 53.

[31] The address of Discount Tobacco # 2 is listed as 137 N. Lee St; the address of Discount Tobacco is listed as 107 South Lee St. RX 12, at 111.

by law.'' *Id.* Putting aside the statement that iodine tincture was not regulated, the Government produced no evidence that this document was ever provided to Mr. Sayani.

To counter the Government, Respondent introduced a copy of a Notice of Proposed Rulemaking (NPRM) in which the Agency proposed ''the control of chemical mixtures containing greater than 2.2 percent iodine.'' DEA, *Changes in the Regulation of Iodine Crystals and Chemical Mixtures Containing Over 2.2 Percent Iodine*, 71 FR 46144, 46145 (Aug. 11, 2006); RX 28. The NPRM expressly stated that ''[i]odine two percent tincture and solution U.S.P. are sold at a wide variety of retail outlets and have household application as antiseptic and antimicrobial products. These products will not become regulated under the proposed regulation.'' 71 FR at 46146. The NPRM further noted that ''[w]hile the regulatory controls placed on iodine apply to iodine crystals, *they have not pertained to iodine tinctures (which are considered chemical mixtures).*'' *Id.* (emphasis added).

In discussing the rationale for the proposed rule, the NPRM further explained that because ''seven percent iodine tincture and solutions are the predominant iodine-containing chemical mixtures diverted by traffickers * * * these chemical mixtures should be subject to CSA chemical regulatory controls.'' *Id.* at 46149. The NPRM then noted that ''[t]wo percent iodine tincture and solutions are also diverted, but DEA has not documented the frequent diversion of these materials at clandestine laboratories. Therefore, DEA does not intend to regulate the two percent iodine tincture or solution at this time.'' *Id.*

Respondent also called as a witness a sales representative for the company which supplied him with iodine tincture. The sales rep. testified that he had sold Respondent iodine tincture with an iodine concentration of only one to two percent, Tr. 437–38, and there is no evidence refuting this. *See* RX 11a & b. The sales rep. further testified that it was his understanding that a DEA registration was not required to sell these products, and that while he had been selling the products for eight to nine years, he had ''no idea'' that iodine tincture was being diverted into the illicit manufacture of methamphetamine. Tr. 439 & 442.

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 [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). Moreover, under section 303(h), ''[t]he Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest.'' 21 U.S.C. 823(h). In making the public interest determination, Congress directed that the following factors be considered:

(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 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).

While I reject the Government's allegations based on Respondent's sales of iodine tincture, I nonetheless conclude that the evidence under factors one, four, and five make out as *prima facie* case that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h). Moreover, while I acknowledge that Respondent has improved its physical security, it has otherwise failed to demonstrate that it has adequate procedures in place to protect the public from the diversion of listed chemical products. Finally, I find especially disturbing Respondent's conduct in continuing to sell large quantities of listed chemical products even after the service of the initial Show Cause Order.

Finally, I reject Respondent's argument that revoking his registration would violate its constitutional right to due process because it has not sold listed chemicals ''in excess of the quantities authorized in the published rules * * * of the DEA.'' Resp. Prop. Findings at 16. I also find unavailing his claim—based on the ALJ's finding that his inventory procedures were inadequate—that it ''is once again being asked to comply with something that is not in the DEA rules,'' and that this is another violation of its right to due process. Resp. Exceptions at 6. Accordingly, Respondent's Forest Park registration will be revoked; its pending renewal application for its Forest Park facility and its application for a registration at its Decatur facility will also be denied.

Factor One—Maintenance of Effective Controls Against Diversion

Under DEA precedent and regulations, this factor encompasses a variety of considerations and is not limited to whether the registrant maintains adequate physical security of listed chemical products. ALJ at 29–30. A DEA regulation requires the consideration of the adequacy of a registrant's ''systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.'' 21 CFR 1309.71(b)(8). Relatedly, a registrant must exercise a high degree of care in monitoring its customer's purchases. *Rick's Picks*, 72 FR 18275, 18278 (2007), *John J. Fotinopoulos*, 72 FR 24602, 24605 (2007), *D & S Sales*, 71 FR 37607, 37610 (2006); *Joy's Ideas*, 70 FR 33195, 33197–98 (2005).

It is undisputed that Respondent upgraded its physical security by building storage cages, installing video cameras, and assigning a person to distribute the products from the cage. This, however, is only one part of a registrant's obligation to maintain effective controls against diversion.

Here, the record shows that Respondent's procedures for verifying the legitimacy of its listed chemical customers were wholly inadequate to prevent diversion. Moreover, those procedures remain so. While following the meeting in which agency investigators notified Respondent of their concerns regarding the legitimacy of its customers, Respondent's counsel stated that it had ''tightened up'' its procedures and was requiring that its customers produce a tax identification number and business license, RX 8, at 1–2 2, these documents can be easily obtained by anyone. While Mr. Sayani

testified that this provided ''enough proof'' that his customers were ''legitimate,'' he did not have an employee personally visit a new customer to determine whether it was a legitimate business with a need for listed chemical products.

Moreover, Respondent generally operated as a ''cash and carry'' business and only delivered if a customer ordered at least $ 1,000 worth of the items and requested that it do so. Thus, a customer could be obtaining listed chemical products from multiple sources and Respondent would have no knowledge of this. *See Holloway Distributing*, 72 FR 42118, 42124 (2007) (noting a registrant's obligation to determine whether a customer is receiving listed chemical products from other suppliers).

As the results of the customer verifications demonstrate, Respondent was indifferent to its obligation to determine whether a potential list I customer had a legitimate need for the products. Moreover, Mr. Sayani's testimony indicates that Respondent did not change its practices. Indeed, Respondent's practices are fundamentally inconsistent with its obligations as a registrant, and are a prescription for wide-spread diversion. *Id., see also D & S Sales*, 71 FR at 37610. Respondent's unwillingness to reform them provides reason alone to conclude that it does not—and will not—maintain effective controls against diversion and that its registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Buttressing this finding is the evidence pertaining to the audit. As found above, the audit, which covered a six-month period, found that Respondent had massive shortages of several listed chemical products including 7640 sixty-count bottles of Head Up, 3656 sixty-count bottles of Max Brand, and 284 sixty-count bottles of Mini 2-Way Action.[32] *See* GX 31. In total, Respondent was short 11,580 sixty-count bottles of pseudoephedrine and combination ephedrine products, or nearly 695,000 dosage units. This was so notwithstanding that the DIs used 0 as the opening inventory for each of the products (the consequence of this is that if any product had, in fact, been on hand on the opening date of the audit, the audit would result in an undercount of the shortage), and that the time period was of limited duration.

Based on the ALJ's finding that its ''lack of an inventory system, alone, provides persuasive weight against Respondent's continued registration,'' ALJ at 30 n.6, Respondent argues that ''there is no requirement under any of the DEA rules to have an inventory system, and [that it] is * * * being asked to comply with something that is not in the DEA rules.'' Resp. Exceptions at 6. Respondent contends that it is ''being held to * * * unpublished DEA guidelines,'' and that this is ''a violation of due process * * * and equal protection guarantees.'' *Id.*

Respondent is correct that there is no regulation which explicitly requires that it maintain an inventory system. However, in enacting section 303(h), Congress made plain that in determining the public interest, the Attorney General was to consider the applicant's (and in a revocation/suspension proceeding, the registrant's) ''maintenance * * * of effective controls against diversion of listed chemicals into other than legitimate channels.'' 21 U.S.C. 823(h).

Moreover, in 1995, DEA promulgated 21 CFR 1309.71(a), which directed that ''[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of List I chemicals.'' This regulation, which remains in effect, further explained that ''[i]n evaluating the effectiveness of security controls and procedures, the Administrator shall consider * * * [t]he adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.'' 21 CFR 1309.71(b)(8).

Federal law further requires that a registrant report ''any regulated transaction involving an extraordinary quantity of a listed chemical,'' 21 U.S.C. 830(b)(1)(A), and a ''regulated transaction'' is based on ''the quantitative threshold or the cumulative amount for multiple transactions within a calendar month.'' 21 CFR 1310.04(f). Federal law also requires a distributor to report to this Agency ''any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person.'' 21 U.S.C. 830(b)(1)(C). Accordingly, to satisfy 21 CFR 1309.71(b)(8), a registrant's recordkeeping must be sufficient so as to enable it to comply with its reporting obligations under Federal law.[33] *See Fotinopoulos*, 72 FR at 24605.

Here, Respondent has no satisfactory explanation as to the disposition of approximately 11,580 sixty-count bottles or 695,000 dosage units of listed chemical products. Whether the shortages are due to poor recordkeeping, theft, or some other reason, the magnitude of these shortages provides a further reason to conclude that Respondent does not maintain effective controls against diversion and that its continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Factor Four—Respondent's Past Experience in Distributing Listed Chemicals

Under this factor, the ALJ further concluded that Respondent made ''excessive sales of both list one chemical products and iodine'' that ''pose a risk to the public interest.'' ALJ at 32. While the ALJ found the testimony of Respondent's expert ''more persuasive'' than the Government's evidence on the expected sales level of list I chemical products, as she further explained, even the Respondent's expert witness ''concurred that some of the [sales of] Respondent's List I chemical products * * * were in excess of what would be expected.'' Id. at 33. While I adopt the ALJ's conclusions with respect to list I chemicals, I reject them with respect to iodine.

With respect to its distributions of iodine, the ALJ found that ''Respondent has knowingly distributed large amounts of 2% iodine, another methamphetamine precursor.'' ALJ at 32. In support of her conclusion, the ALJ relied on the testimony of Respondent's expert that there were ''five instances where the quantity [of iodine] purchased might be suspiciously high,'' Tr. 571, as well as on Mr. Sayani's testimony that he was aware that one of his customers was purchasing hundreds of bottles but that he thought the customer was distributing to other small retailers. *Id.* at 744; *see also* ALJ at 32.

The Government's own evidence establishes, however, that the 2% iodine product which Respondent sold ''is not regulated by law,'' GX 36B at 2, and the NPRM which announced the Agency's intent to regulated iodine tinctures containing more than 2.2 percent iodine noted that 2% iodine tincture products ''are sold at a wide variety of retail outlets and have household application as antiseptic and antimicrobial products.'' 71 FR 46146. The same NPRM also explained that the ''frequent diversion'' of two percent iodine tincture at clandestine laboratories ''has not [been] documented.'' *Id.* at 46149.

[32] Respondent also had substantial shortages of three other products. GX 31.

[33] Typically, this requires no more than maintaining the records that a registrant keeps in the normal course of business. *See, e.g.* , DEA, *Implementation of the Domestic Chemical Diversion Control Act of 1993*, 60 FR 32447, 32451 (1995) (noting ''that most of the information required by the regulations is already maintained in general business records for all transactions'').

Furthermore, DEA's regulations provide that two conditions must be met for a chemical mixture to be exempted from regulation. 21 CFR 1310.13(a). First, ''[t]he mixture [must be] formulated in such a way that it cannot be easily used in the illicit production of a controlled substance.'' *Id.* § 1310.13(a). Second, ''[t]he listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.'' *Id.* § 1310.13(b). Given the criteria for exempting a chemical mixture from regulation, neither the ALJ nor the Government explained why large sales of 2% iodine tincture are, by themselves, enough to give rise to a reasonable belief that the chemical contained therein is likely to be diverted.

Here, there is no evidence that Respondent sold these products with knowledge that they would be diverted for use in the illicit manufacture of methamphetamine, and in any event, the Government's allegation that Respondent was selling excessive amounts of iodine tincture is not supported by substantial evidence. The Government's evidence is limited to the testimony of a diversion investigator that she had visited 100 convenience stores and had never found iodine tincture. Yet the Agency's NPRM noted that these products, which have several legitimate uses, are sold at ''a wide variety of retail outlets.'' 71 FR at 46146.

More importantly, even assuming that the investigator was specifically looking for iodine tincture at the convenience stores she visited, the testimony amounts to nothing more than anecdotal evidence. As such, it does not conclusively establish the extent to which these products are sold at convenience stores and the statistical improbability that Respondent's sales of these products were to meet legitimate demand. Indeed, the evidence stands in contrast to the quantum of the evidence the Government introduced regarding the expected sales levels of list I chemical products at convenience stores.[34] Accordingly, I conclude that Respondent's sales of iodine do not support a finding that its continued registration is inconsistent with the public interest.

On the other hand, Respondent's sales of list I chemical products clearly were excessive and support a finding that its continued registration is inconsistent with the public interest. Even assuming that the monthly expected sales figure of $173 for pseudoephedrine given by Respondent's expert is accurate, and that some stores might make a legitimate business decision to purchase a case quantity to reduce their costs, the evidence shows that Respondent repeatedly sold case quantities to multiple customers including the Coastal Food Mart, Chitra Inc.'s Quick Stop, the Phillips 66 Mart, the R & S Grocery, and the Stop In.

The evidence also shows that Respondent sold case quantities to two customers which gave the same address. For example, between January 6 and August 1, 2004, Respondent sold a total of eleven cases to the P & K Mini Mart and the Quick Stop/Tushar/BP, both of which used the same address. Moreover, between January 6 and September 5, 2004, it sold a total of fifteen cases to the DJ Food Mart and BJ Food Market #1, which gave their respective addresses as 15582 HWY 27 and 15582 HWY 27 North in Trion, Georgia.

With respect to the Coastal Food Mart, which purchased eight cases between January 21 and September 5, 2004, even Respondent's expert acknowledged that this store's purchases were many times the expected norm. Tr. 619–20. And as found above, several of Respondent's customers purchased even larger amounts of list I chemical products than did the Coastal Food Mart. As Respondent's expert allowed with respect to those customers who were repeatedly purchasing large quantities, ''maybe there's some nefarious practice involved here'' and the customers are ''doing something that * * * they shouldn't be doing.'' *Id.* 570.[35]

Respondent raises two arguments in response to the allegations that it sold excessive quantities of list I chemical products. First, it argues that given the nature and size of its business, it would be ''almost impossible to find'' the excessive sales. Resp. Prop. Findings at 15.

Second, it argues that is ''has not sold any restricted item in excess of the quantities authorized in the published rules and regulations * * * which show the threshold quantities of restricted items the wholesalers * * * are allowed to sell without * * * putting their DEA license at risk.'' *Id.* at 16. Relatedly, Respondent raises again a due process argument that ''[i]f the Government is proceeding on any basis other than Respondent having exceeded the sale quantity thresholds which the Government has specifically published (such as 'not in the public interest'), then the Government is proceeding under a rule or statute which is void for vagueness as it does not put Respondent on notice as to what specific action would be violative of [its] rules and regulations.'' *Id.* at 17–18.

As for the argument that it would be nearly impossible to detect excessive purchases, Respondent's expert acknowledged that a computer program could be written to detect such purchases. Tr. 648. Nor would it require more than minimal effort to call up a customer's account to determine the frequency and amounts of its purchases before selling additional amounts of the products to it.

Also unavailing is Respondent's contention that because it did not sell more than the threshold quantities, its registration cannot be revoked. Contrary to Respondent's understanding, selling under threshold amounts does not relieve a registrant from its obligation to taking necessary measures ''to determine the ultimate disposition of [its] products.'' *Rick's Picks*, 72 FR at 18278. The thresholds simply trigger additional recordkeeping and reporting requirements. As I explained in *Rick's Picks:*

> Congress's imposition of recordkeeping and reporting requirements for regulated transactions does not mean that one can engage in below-threshold transactions without any further obligation to determine whether the products are likely to be diverted. Indeed, DEA has found that products which have been distributed to non-traditional retailers in sub-threshold transactions are routinely diverted. Contrary to Respondent's view, the threshold provisions pertaining to regulated transactions do not create a safe harbor which allows a registrant to sell list I chemicals without any further duty to investigate how the products are being used.

Id. Cf. United States v. *Kim*, 449 F.3d 933, 944 (9th Cir. 2006) (''[T]he recording and reporting statutes establish no safe harbor from prosecution under [21 U.S.C.] 841(c)(2).''). I therefore reject Respondent's contention (as raised in both its Exceptions and Motion for Judgment as a Matter of Law) that this proceeding should be dismissed because it did not sell in excess of the thresholds.

Finally, there is no merit to Respondent's related contention that it has been denied fair ''notice as to what specific action would be violative of [DEA's] rules and regulations.'' Resp. Prop. Findings at 18. Contrary to

[34] Because 2% iodine tincture is not regulated, the Government's allegation that it engaged in regulated transactions which it failed to report as suspicious transactions is also rejected.

[35] As DEA has found in numerous other cases, where there is a pattern of distributions which are so large as to be statistically improbable to meet legitimate demand, a finding that the products have been diverted is warranted. *See Holloway Distributing*, 72 FR at 42125; *T. Young Associates, Inc.*, 71 FR 60567, 60572 (2006); *D & S Sales*, 71 FR at 37611; *Joy's Ideas*, 70 FR at 33198.

Respondent's view, the standards, which it was expected to conform to, were identifiable ''with ascertainable certainty'' by reviewing DEA's public pronouncements. *Trinity Broadcasting, Inc.*, v. *FCC*, 211 F.3d 618, 628 (D.C. Cir. 2000).

In section 304(a), Congress made clear that a registration is subject to revocation where a registrant ''has committed such acts as would render his registration * * * inconsistent with the public interest as determined under'' under section 303. 21 U.S.C. 824(a)(4). And in section 303(h), Congress clearly provided that one of the criteria for determining the public interest is whether a registrant maintains ''effective controls against diversion of listed chemicals into other than legitimate channels.'' *Id.* § 823(h)(1). The statute itself thus provides fair warning to a registrant that is must not sell to diverters.

Moreover, in several decisions which pre-dated nearly all of the listed chemical distributions discussed above, this Agency made clear that selling in quantities that greatly exceed legitimate demand for these products supports a finding of diversion and that such conduct can be the basis for the revocation of a registration. *See, e.g., Branex, Inc.,* 69 FR 8682, 8690–94 (2004) [36] (revoking registration noting that distributor's sales of pseudoephedrine to convenience stores greatly exceeded the expected sales range at such stores and supported a finding that the pseudoephedrine was likely diverted); *MDI Pharmaceuticals*, 68 FR 4233, 4238 (2003) (revoking registration on ground that ''firm distributed large quantities of pseudoephedrine tablets to smoke shops and * * * convenience stores in quantities that apparently exceeded legitimate demand for these products''); *Ace Wholesale & Trading Co.*, 67 FR 12574, 12576 (2002) (revoking registration on grounds that registrant ''was distributing large quantities of pseudoephedrine to [a convenience store] and other establishments that appeared far in excess of legitimate demand'').[37] In these decisions, all of which were also published on the Agency's Web site as well as in the **Federal Register**, DEA provided fair warning that Respondent's conduct in selling large quantities of listed chemicals could result in the revocation of its registration.

Respondent's argument rings hollow for another reason. In the first Show Cause Order, Respondent was put on notice that ''Max Brand products have been found on numerous occasions in situations related to the illicit manufacture of methamphetamine,'' Show Cause Order I, at 3; that the monthly expected sales range of pseudoephedrine products at convenience stores in Georgia ''averaged between $15 and $60,'' *id.* at 4; and that its sales of listed chemical products were ''wildly inconsistent with the expectation of sales'' by convenience stores. *Id.* at 5. Mr. Sayani even testified under oath that at the ''end of 2004, starting of 2005,'' and after receiving the Show Cause Order, he had stopped selling Max Brand products. Tr. 713. Respondent's records establish, however, that it continued to sell the products for months past the date when Mr. Sayani claimed it had stopped; it also shows numerous instances in which Respondent sold half-case quantities or larger for several months thereafter.[38] I thus reject Respondent's contention that it lacked fair warning that its excessive sales could be grounds for the revocation of its registration.

Accordingly, while Respondent was authorized to distribute list I chemicals for approximately six years, its experience is characterized by its frequent disregard of its obligation to protect against the diversion of these products. This conclusion provides an additional basis, which is sufficient by itself, to find that Respondent's continued registration is ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Factor Five—Such Other Factors as Are 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.[39] Cutting off the supply sources of methamphetamine traffickers is of critical importance in protecting the public from the devastation wreaked by this drug.

While listed chemical products containing both ephedrine and pseudoephedrine have legitimate medical uses, DEA orders have established that convenience stores, gas-stations, and other small retailers, constitute the non-traditional retail market for legitimate consumers of products containing these chemicals. *See, e.g., Tri-County Bait Distributors*, 71 FR 52160, 52161–62 (2006); *D & S Sales*, 71 FR at 37609; *Branex, Inc.*, 69 FR 8682, 8690–92 (2004). 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'' if application to distribute to non-traditional retailers was granted). For this reason, DEA has repeatedly revoked the registrations and denied an application for registration when a registrant distributes (or an applicant proposes to distribute) listed chemicals to non-traditional retailers and other evidence (such as excessive sales, inadequate diversion controls, previous violations/criminal convictions or a lack of adequate experience) confirm that the registrant/applicant is unlikely to responsibly handle the products. *See Rick's Picks*, 72 FR at 18278–80; *John J. Fotinopoulos*, 72 FR at 24605–07; *Tri-County Bait Distributors*, 71 FR at 52163–64; *D & S Sales*, 71 FR at 37610–12; *Joy's Ideas*, 70 FR at 33197–99; *Xtreme Enterprises*, 67 FR 76195, 76197–98 (2002).

The record here likewise establishes a substantial nexus between the sale of non-traditional list I chemicals products and the diversion of these products into the illicit manufacture of

[36] The *Branex* decision was published in the **Federal Register** on February 25, 2004, before Respondent made many of the case quantity distributions.

[37] In addition, in publications such as the *Chemical Handler's Manual*, DEA explained that ''[i]t is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature.''*Chemical Handler's Manual* 15 (2002).

The *Chemical Handler's Manual* also sets forth numerous criteria for recognizing suspicious transactions including ''resell[ing] to non-traditional outlets for regulated OTC products, e.g., hair salons, head shops, drug paraphernalia stores, liquor stores, record stores, video shops, auto parts stores,'' and ''resell[ing] large volumes into the 'independent convenience store' market.'' *Id.* at 42. The manual also listed as relevant criterion ''[a]ny customer who asks for large bottle sizes, 60 count or higher,'' or ''buy[s] only the largest size available.'' *Id.*

[38] Relatedly, Mr. Sayani told the DI during one of the 2001 inspections that ''a typical sale'' would be two to three boxes containing 12 bottles; in the same conversation, the DI told Mr. Sayani that a sale of a case quantity would be suspicious. Tr. 330–31. Many of Respondent's sales were well in excess of a typical sale. Respondent thus not only ignored the DI's instruction, it also ignored its own understanding of the market. Moreover, at the various visits, Respondent was provided with a copy of several notices which explained that pseudoephedrine and combination ephedrine were being diverted into the illicit manufacture of methamphetamine.

[39] As found above, methamphetamine trafficking has increased substantially in Georgia and the adjacent States.

methamphetamine. According to the testimony of a DEA Special Agent, who had debriefed more than 200 individuals involved in the illicit manufacture of methamphetamine, convenience stores, gas stations and other small retailers were the primary and preferred source of pseudoephedrine and ephedrine that was used by smaller meth. labs. Tr. 56 & 59; *see also TNT Distributors*, 70 FR 12729, 12730 (2005) (noting Special Agent's testimony that ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores'').

The record establishes that Respondent's list I customer base was comprised primarily of the same type of establishments. More specifically, Respondent's list I customers included gas stations, convenience stores, dollar stores, liquor stores, beauty stores, gift shops, and some customers (such as those located at private residences) whose business was not even clear. As the ALJ observed ''[s]ome of these businesses did not even appear to be tangentially related to the legitimate sale of pseudoephedrine and ephedrine products.'' ALJ at 34. As the ALJ further noted, notwithstanding the substantial risk of diversion present when distributing to these establishments, as well as the testimony that non-traditional retailers were the primary supply source for illicit meth. cooks, Respondent offered no evidence that it ''would cease dealing with'' these establishments. *Id.*

Moreover, while Respondent disputed the amount of monthly sales of pseudoephedrine at convenience stores to meet legitimate demand, it did not challenge the Government's evidence that sales of non-prescription drugs account for only a small percentage of the total sales of convenience stores that handle the products. Nor did it offer any evidence to refute the Government's evidence that only a small number (approximately two in one thousand) of convenience store customers purchase a pseudoephedrine product. And even using the monthly expected sales figures put forth by its expert, as found above, Respondent repeatedly sold to multiple non-traditional retailers quantities of list I chemical products that greatly exceeded legitimate demand for these products.

Having concluded that the Government made out its *prima facie* case, the ALJ then turned to assessing whether Respondent had produced sufficient evidence that it would protect the public interest from the diversion of the products. *Id.* at 34. As the ALJ noted, Respondent did improve its physical security. *Id.* The ALJ also noted that Respondent had conducted ''some investigations into some of its customer's business identities.'' *Id.* Yet at the hearing, Mr. Sayani testified that he did not go to a new customer's store to verify whether it was a legitimate business and that a new customer's presentation of a tax identification number and business license provided sufficient proof of the customer's bona fides. Tr. 768–69. Mr. Sayani offered no testimony that Respondent was willing to change this practice.[40]

The ALJ nonetheless concluded that Respondent ''does demonstrate a willingness to comply with DEA directions'' because it did not handle list I chemical products at its Decatur location while its application was pending and at its Forest Park location after that registration was suspended. ALJ at 34–35. The ALJ also reasoned that Respondent ''stopped selling non-traditional listed chemical products in 2004, after the DEA served its first Order to Show Cause.'' *Id.* at 35.

Both the handling of a list I chemical product at an unregistered location and the distribution of a list I product out of a location with a suspended registration would, however, constitute felony offenses under Federal law. *See* 21 U.S.C. 841(f)(1); *id.* § 843(a)(9); *id.* § 844(a). Even if Respondent's compliance with these provisions is probative of its willingness to cooperate (a debatable proposition given that its non-compliance would expose it to substantial criminal penalties), the remaining basis for the ALJ's conclusion is not supported by the record.

As found above, Respondent continued selling non-traditional products—and made numerous large quantity transactions—well into April 2005, approximately five to six months after service of the first Show Cause Order. Indeed, Mr. Sayani's testimony regarding when Respondent stopped selling the products is clearly refuted by the documentary evidence. The weight of the evidence thus does not support the ALJ's conclusion that Respondent is willing to comply with DEA's direction.

In any event, notwithstanding her finding, the ALJ concluded that Respondent's ''cooperation is dwarfed by the significant risk of diversion posed to the public by * * * Respondent's continued sales of listed chemical products to [non-traditional retailers] without adequate sales records or customer verification.'' ALJ at 35. While Respondent contends that the ALJ ''ignore[d] the substantial remedial actions that [it] had taken to correct [the] problems of which'' it was notified, Resp. Exceptions at 6, the ALJ considered them and properly concluded that they only partially addressed the problems identified by the Agency. *See* ALJ at 35 (noting that Respondent has ''not provided sufficient evidence to convince [the Agency] that its future conduct would change to the degree necessary to eliminate the threat to the public interest'').

In short, Respondent offered no evidence of its willingness to change its practices for determining whether its customers are legitimate. It offered no evidence that it has in place systems to accurately account for the products it handles and to properly identify those customers who are purchasing excessive quantities.

Likewise, it has offered no credible evidence that it is willing to change its practices to limit its sales of these products. Its claim that it stopped selling the products shortly after service of the first Show Cause Order, is contradicted by the documentary evidence. Moreover, its argument that the thresholds establish the ''quantities of restricted items the wholesalers * * * are allowed to sell without * * * putting their DEA license at risk, [and] are what both the Government and the public are bound to abide by,'' Resp. Prop. Findings at 16—a theme which is repeated throughout its brief—makes plain its view that it can continue to sell up to the thresholds with no obligation to limit its distributions to those establishments at which there is only limited consumer demand for these products for their lawful use. Because this view is fundamentally inconsistent with a distributor's obligation under the CSA, I conclude that Respondent's registration ''is inconsistent with the public interest.'' 21 U.S.C. 823(h).[41]

[40] There was also evidence that on one occasion, Respondent's attorney reported an incident involving an individual who, in attempting to purchase products, admitted to Mr. Sayani that he did not have a store, and then showed Mr. Sayani a van full of products which he had purchased from a competitor of Respondent. RX 29. While the letter provided information regarding the practices of Respondent's competition, it did not report the name of the individual or give the license plate number (or a description) of the van. *See id.*

[41] Respondent also contends that ''the Government had no reasonable justification in summarily proceeding to seize his products and summarily revoke his license without affording him a due process right to a hearing.'' *Id.* at 20. Respondent ignores, however, that section 304(d) of the CSA expressly authorizes the suspension of ''any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health and safety.'' 21 U.S.C. 824(d).

Continued

Order

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 order that DEA Certificate of Registration, 040450SLY, issued to Sunny Wholesale, Inc., 120 Forest Parkway, Forest Park, Georgia, be, and it hereby is, revoked, and that its application to renew this registration be, and it hereby is, denied. I further order that Sunny Wholesale, Inc.'s, application for a DEA Certificate Registration at 2935 N. Decatur Road, Suite C, Decatur, Georgia, be, and it hereby is, denied. These orders are effective November 3, 2008.

Dated: September 26, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–23395 Filed 10–2–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

September 26, 2008.

The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Amy Hobby on 202–693–4553 (this is not a toll-free number)/email: *DOL_PRA_PUBLIC@dol.gov*.

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment Standards Administration (ESA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316 / Fax: 202–395–6974 (these are not toll-free numbers), E-mail: *OIRA_submission@omb.eop.gov* within 30 days from the date of this publication in the **Federal Register**. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment Standards Administration.

Type of Review: Extension without change of an existing OMB Control Number.

Title of Collection: Requirements of a Bona Fide Thrift or Savings Plan (29 CFR Part 547) and Requirements of a Bona Fide Profit-Sharing Plan or Trust (29 CFR Part 549).

OMB Control Number: 1215–0119.

Affected Public: Businesses or other for-profits, Farms, Not-for-profit institutions.

Total Estimated Number of Respondents: 844,000.

Total Estimated Annual Burden Hours: 352.

Total Estimated Annual Costs Burden: $0.

Description: This information collection applies to employers claiming the overtime exemption available under section 7(e)(3)(b) of the Fair Labor Standards Act. Specifically, in calculating an employee's regular rate of pay, an employer need not include contributions made to a bona fide thrift or savings plan or a bona fide profit-sharing plan or trust—as defined in 29 CFR Parts 547 and 549. Employers are required to communicate, or make available to the employees, the terms of the bona fide thrift or savings plan and bona fide profit-sharing plan or trust, and retain certain records. For additional information, see related notice published at 73 FR 39725 on July 10, 2008.

Darrin A. King,

Departmental Clearance Officer.

[FR Doc. E8–23101 Filed 10–2–08; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,583; TA–W–62,583A]

PeopLoungers, Inc., Nettleton, MS, and PeopLoungers, Inc., Mantachie, MS; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on April 2, 2008, applicable to workers of PeopLoungers, Inc., Nettleton, Mississippi. The notice was published in the **Federal Register** on April 17, 2008 (73 FR 20954).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of furniture.

New information provided by the company official shows that after the worker group was certified eligible to apply for adjustment assistance, the subject firm relocated remaining workers and production from Nettleton, Mississippi to Mantachie, Mississippi.

Based on this finding, the Department is amending the certification to include workers separated from the Mantachie, Mississippi location of PeopLoungers, Inc.

Respondent does not argue that the statute is unconstitutional. Nor could it, as the Supreme Court has repeatedly upheld the use of post-deprivation process in emergency situations. *See, e.g., Gilbert* v. *Homar,* 520 U.S. 924 (1997). Moreover, in this case, the evidence of Respondent's continued large sales of listed chemical products, even after being served with the first Show Cause Order, supports the finding that Respondent's continued registration during the pendency of the proceeding posed an imminent danger to public health and safety. Respondent could also have sought review of the suspension in a ''court of competent jurisdiction.'' 21 U.S.C. 824(d).

Finally, Respondent asserts that ''the effect of the DEA's arbitrary actions [in its] case [is] to discriminate against him because he is a legal alien'' in violation of his right to equal protection of the laws. Resp. Prop. Findings at 25. Respondent does not, however, contend that the Agency is intentionally discriminating against its owner, *see Hernandez* v. *New York,* 500 U.S. 352, 359–60 (1991), a requirement for stating a claim under the Equal Protection Clause, and in any event, it has produced no evidence to support its claim. Respondent is just one of many list I chemical distributors whose registrations have been revoked for committing acts inconsistent with the public interest.