the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *id.* at 1459–60. As this Court recently confirmed in SBC Communications, courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' SBC Commc'ns, 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). The language wrote into the statute what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' SBC Commc'ns, 489 F. Supp. 2d at 11.[5]

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: August 28, 2008.

Respectfully submitted,

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Certificate of Service

I hereby certify that on August 28, 2008, I caused a copy of the foregoing Competitive Impact Statement to be served on the defendant in this matter in the manner set forth below:

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–33]

Novelty Distributors, Inc.; Revocation of Registration

On January 17, 2008, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Novelty Distributors, Inc. (Respondent), of Greenfield, Indiana. The Order immediately suspended and proposed the revocation of Respondent's DEA Certificate of Registration, 003563NSY, as a distributor of the list I chemicals ephedrine and pseudoephedrine, on the grounds that its ''continued registration is inconsistent with the public interest,'' and ''constitute[d] an imminent danger to public health and safety.'' Show Cause Order at 1 (ALJ EX. 1) (citing 21 U.S.C. 823(h), 824(a)(4), and 824(d)).

More specifically, the Show Cause Order alleged that Respondent was storing listed chemical products at, and distributing them from, over 100 unregistered locations throughout the United States, in violation of Federal law and regulations. *Id.* (citing 21 U.S.C. 822(e), 21 CFR 1309.21 and 1309.23(a)).

Next, the Show Cause Order alleged that Respondent was distributing quantities of listed chemical products ''to small retail outlets such as convenience stores'' in amounts ''far exceed[ing] what those retail outlets could be expected to sell for legitimate, therapeutic purposes.'' *Id.* at 2. The Order thus alleged that the ''listed chemical products distributed by [Respondent] in large quantities have been, and are likely to continue being, diverted to the clandestine manufacture of methamphetamine.'' *Id.* (citing cases). Relatedly, the Show Cause Order alleged that some ''[s]mall retail outlets that receive large quantities of * * * listed chemical products from [Respondent] sell such products to individuals in amounts that cannot be attributed to legitimate individual needs,'' that ''some of the retail outlets allow customers to make multiple purchases of scheduled listed chemical products within a single week, and in some cases, within a single day,'' and that ''[s]ome customers of these retail outlets purchased more than 9 grams of ephedrine or pseudoephedrine base within 30 days in violation of 21 U.S.C. 844(a).'' *Id.*[1]

The Show Cause Order further alleged that between January 1, 2007, and July 9, 2007, Respondent distributed listed chemical products ''on at least 284 occasions to 35 retail outlets,'' which had not self-certified as required under Federal law. *Id.* (citing 21 U.S.C. 830(e)(1)(A)(vii)). *Id.* Moreover, on three occasions subsequent to February 1, 2007, Respondent allegedly distributed 24-count bottles of listed chemical products to retailers in violation of Federal law, which effective April 9, 2006, required that non-liquid form products be sold only in blister packs. *Id.* at 2–3 (citing 21 U.S.C. 830(d)(2)). Relatedly, the Show Cause Order alleged that Respondent had distributed tablet-form products to retailers in Kentucky and North Carolina in violation of the laws of these States which ''prohibit the sale of non-liquid ephedrine and pseudoephedrine except in a gel-cap product.'' *Id.* at 3.

Finally, the Show Cause Order alleged that in July 2007, DEA had audited twenty listed chemical products which Respondent distributed. *Id.* at 2. The Show Cause Order alleged that Respondent ''could not account for more than 60,000 dosage units of two ephedrine products'' and that it also had ''overages for 16 different * * * listed chemical products.'' *Id.* The Order thus alleged that Respondent ''failed to maintain accurate records of its distributions and receipts of * * * listed chemical products in violation of 21 U.S.C. 830(a) and 21 CFR 1310.04.'' *Id.*

[5] See 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am. Dairymen, Inc.*, 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93–298, 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

[1] The Show Cause Order also alleged that ''[i]n November 2002, 22 bottles of ephedrine products distributed by Novelty were found at an illicit methamphetamine laboratory in Connecticut.'' Show Cause Order at 2.

Based on the above allegations, I made the preliminary finding that the listed chemical products Respondent was distributing had been, and were ''likely to continue to be, diverted into the illicit manufacture of methamphetamine.'' *Id.* at 3. I also found that Respondent's ''failure to maintain effective controls against diversion, including its distribution of large amounts of * * * listed chemical products that far exceed legitimate demand, contribute to the illicit manufacture of methamphetamine.'' *Id.* I thus came to the ''preliminary conclusion that [Respondent's] continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety,'' and immediately suspended its registration. *Id.*

On February 26, 2008, Respondent requested a hearing on the allegations. ALJ Ex. 2. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who proceeded to conduct pre-hearing procedures. A hearing was held on March 24 through March 28, and March 31 through April 2, 2008, at which both parties put on extensive testimony and introduced numerous documents into evidence.

Moreover, on March 24, 2008, Respondent filed an interlocutory appeal in which it challenged the ALJ's denial of its motion to remove one of the Government's lawyers from participating in the hearing, on the ground that he was a necessary and indispensable witness to the events surrounding the execution of an administrative search warrant which was the subject of its motion to suppress. *See* ALJ Exs. 12 and 13. On March 25, 2008, I denied Respondent's appeal on multiple grounds.[2] ALJ Ex. 13.

Following the hearing, both parties submitted briefs containing their proposed findings, conclusions of law, and argument. On May 21, 2008, the ALJ issued her recommended decision (hereinafter, ALJ).[3]

In her decision, the ALJ found that the Government's evidence regarding the monthly expected sales of combination ephedrine products at convenience stores ($14.39) to meet legitimate demand was ''flawed and not credible.'' ALJ at 97. Relatedly, while acknowledging that ''Respondent sells an approximate monthly average of $640.00 in SLC products to its convenience store customers,'' the ALJ observed that ''there is no legitimate sales figure in the record'' by which the excessiveness of its sales (and the likelihood that the products were being diverted) could be judged. *Id.*

Regarding the allegation that Respondent failed to maintain accurate records of its receipts and distributions, the ALJ concluded that the evidence pertaining to the audit did not establish ''preponderating evidence either way to assist in analyzing the accuracy of * * * Respondent's handling'' of listed chemical products. *Id.* at 88. The ALJ concluded, however, that ''Respondent's recordkeeping is not adequate to conduct an effective audit of its SLC products.'' *Id.*

The ALJ also rejected the allegation that Respondent had made numerous distributions to uncertified retailers based on testimony and documentary evidence that one of Respondent's officials had confirmed that these ''customers were, in fact, self-certified.'' *Id.* at 91. The ALJ further found unproven the allegation that Respondent had thrice distributed listed chemical products in bottles in violation of Federal law, noting that Respondent had provided ''documentary proof that the * * * product * * * had not been illegally distributed.'' *Id.* at 86. The ALJ also found unproven the Government's allegation that Respondent had distributed tablet-form products to retailers in Kentucky and North Carolina, noting that ''Respondent produced credible testimonial evidence to support a finding that these illegal sales in fact did not happen.'' *Id.*

With respect to the allegation that Respondent was violating Federal law because it was distributing from over 100 drop-off points which were not registered, the ALJ noted that Respondent had challenged the Agency's interpretation in Federal District Court. *Id.* at 90–91. The ALJ found, however, that Respondent had been advised by a DEA Group Supervisor (GS) that its practice of shipping SLCs to numerous storage units which were not registered was illegal, that it had continued do so without even seeking clarification from the Agency, and that this conduct was ''not consistent with the requirements for a participant in a regulated industry.'' *Id.* at 91. However, because Respondent's declaratory judgment action was still ''pending in federal court,'' the ALJ ''conclude[d] that [the district court was] the proper venue for this issue'' and declined to address the statutory question.[4] *Id.* at 91 n.38.

Finally, the ALJ also found that following the suspension order, Respondent had attempted to enter into an agreement with one of its suppliers (BDI), under which its salespersons would still take orders for SLCs which would be shipped by BDI. ALJ at 92. Here again, the ALJ noted that there was no evidence that Respondent had asked the Agency if the arrangement was lawful. *Id.*

The ALJ nonetheless concluded that Respondent had ''demonstrated a willingness to comply with the laws and regulations governing the distribution of SLC products,'' specifically noting that it had developed a training program for its customers, had provided them with the logbooks required by the CMEA, and lockable display cases for its products, and had upgraded its computer system. *Id.* at 98–99. The ALJ also noted that following the implementation of the CMEA, Respondent had ''acted to remove * * * non-complying SLC products from its customers' shelves and [to] properly dispose of'' them. *Id.* at 99.

With respect to the audits, the ALJ observed that while they ''appeare[d] to reveal significant overages and shortages,'' Respondent had ''credibly and adequately minimized those figures to a more acceptable margin of inventory error after analyzing its records and making its own audit

[2] The grounds included that Respondent had not established that the Government's lawyer was a necessary and indispensable witness, and that Respondent had not cited a single case to support its contention that the conduct of the Government lawyer—even if true—was a violation of its constitutional rights. Denial of Interlocutory Appeal, at 2–3 (ALJ Ex. 13.) I also noted that the Agency had previously held that the exclusionary rule does not apply to proceedings under 21 U.S.C. 824, and that the Supreme Court had ''repeatedly declined to extend the exclusionary rule to proceedings other than criminal trials.'' *Id.* (quoting *Pennsylvania Bd. of Probation* v. *Scott*, 524 U.S.C. 357, 363 (1998)).

[3] The decision was 165 pages in length.

[4] On August 7, 2008, the District Court granted the Government's motion for summary judgment and denied Respondent's cross-motion for summary judgment. *See* Entry on Cross Motions for Summary Judgment, *Novelty, Inc.,* v. *Tandy*, No. 1:04–cv–1502–DFH–TAB (S.D. Ind., Aug. 7, 2008). Notably, the District Court held that the instructions in the Group Supervisor's letter were interpretive and not legislative rules, and were thus not subject to notice and comment rulemaking under 5 U.S.C. 553. *Id.* at 2. Pursuant to 5 U.S.C. 556(e), I take official notice of the District Court's decision. I also take official notice of the August 13, 2008 letter submitted by Respondent's President. In his letter, Respondent's President stated that he has ordered a change to Respondent's distribution practices and ''reiterates its previously stated commitment to cooperate with [this Agency] and adhere to all conditions specified by [me] for [its] continued registration.'' Letter of Todd Green (Aug. 13, 2008).

In his letter, Respondent's CEO does not state that Respondent's will waive its right to appeal the District Court's decision. Moreover, I conclude that in light of the extensive resources that have been devoted to litigating the issue of the lawfulness of Respondent's use of unregistered locations to store and distribute SLCs, as well as the importance of the issue to the regulated industry, the issue should be decided.

findings.'' *Id.* Finally, while the ALJ noted that Respondent's continued distributions to the drop-off points ''cause[s] concern,'' she further reasoned that except for the Group Supervisor's letter, it ''had no notice from the [Agency] of any violations until the * * * Suspension Order was served'' on it, and that it ''ha[d] not been given an opportunity to remedy the flaws identified by the Agency [in] this action.'' *Id.* at 100. Based on what she characterized as its ''history of,'' and ''financial commitment to,'' compliance, the ALJ reasoned that revocation would not be an appropriate sanction. *Id.* at 100–01. Instead, the ALJ recommended that I impose compliance requirements on Respondent to ensure that it operated in the public interest. *Id.* at 101.

Thereafter, the Government filed exceptions to the ALJ's decision. Respondent likewise filed a 140 page brief which supported the ALJ's decision while also excepting to certain findings and conclusions.

Having considered the entire record in this matter and all of the issues raised in the parties' exceptions, I hereby issue this Decision and Final Order. More specifically, I reject the allegations that Respondent distributed SLC products in violation of the CMEA and the laws of Kentucky and North Carolina as unsupported by substantial evidence. With respect to the allegations that Respondent engaged in 284 distributions to uncertified retailers, I conclude that the evidence establishes only a single instance of distributing to an uncertified retailer and several instances of inaccurate recordkeeping in that Respondent's records of the addresses for several stores did not match the actual addresses of the stores, and that the Government has not proved by substantial evidence that the stores were uncertified on the date of the distributions.

With respect to the audit, I conclude that because the ALJ found credible the testimony of one of Respondent's executives that the Agency's investigators had excluded certain transactions and inventory adjustments which it had provided to them, and the Government offered no rebuttal evidence, the allegation that Respondent had shortages and overages of various products is not proved. I find, however, that the evidence shows that Respondent's recordkeeping did not comply with federal law because it failed to maintain proper records of regulated transactions as required by Federal law and DEA regulations. *See* 21 U.S.C. 830(a); 21 CFR 1310.03, *id.* 1310.04, *id.* 1310.06. Because of this, as well as evidence showing that Respondent's list of shipments included three shipments of a product with a date of July 16, 2007, even though it was then only July 9, 2007, I find that Respondent does not have adequate systems for monitoring the receipt and distribution of SLCs. 21 CFR 1309.71(b).

With respect to the allegation that Respondent's sales of SLC were excessive and consistent with diversion, I agree with the ALJ that the Government's figure as to the expected monthly sales range is not supported by substantial evidence. I nonetheless conclude that Respondent does not maintain effective controls against diversion because its own evidence shows that it distributed SLCs to numerous stores in quantities that dwarfed what its average customer purchases, and that it did so even when it had previously developed concerns that a store was purchasing excessive quantities, and that it does not even enforce its own sales limit policies.

Next, in contrast to the ALJ, I conclude that this proceeding is the appropriate forum to address the meaning of 21 U.S.C. 822(e) and the allegation that Respondent has repeatedly violated Federal law by distributing from unregistered locations. Consistent with the statutory text and purpose, I conclude that Respondent's practice of using unregistered self-storage units to store and distribute SLC products violated the Controlled Substances Act and DEA's regulation.

Finally, for reasons set forth below, I reject the ALJ's recommended sanction that Respondent's registration be continued with conditions. As explained below, because Respondent repeatedly violated Federal law notwithstanding that it was advised that its use of the unregistered self-storage facilities was unlawful, does not even enforce its own policies with respect to limiting sales, and attempted to circumvent the suspension order, I conclude that revocation is necessary to protect the public interest. I make the following findings of fact.

Findings

Respondent is a corporation which is solely owned by its President, Mr. Todd Green. Respondent is a wholesale distributor of various sundry items to between 10,000 and 12,000 convenience stores throughout the United States.

Since 1998, Respondent has held DEA Certificate of Registration, #003563NSY, which authorizes it to distribute pseudoephedrine and ephedrine from its registered location of 351 W. Muskegon Drive, Greenfield, Indiana. GX 1. Respondent's registration expires on October 31, 2008. *Id.*

Both ephedrine and pseudoephedrine have FDA approved therapeutic uses. GX 19, at 3. Ephedrine is lawfully marketed under the Food, Drug, and Cosmetic Act for OTC use as a bronchodilator to treat asthma,[5] and pseudoephedrine is lawfully marketed for OTC use as a decongestant. *Id.* at 3–4. Both substances are, however, regulated as schedule listed chemicals under the Controlled Substances Act because they are precursor chemicals which are frequently diverted into the illicit manufacture of methamphetamine, a schedule II controlled substance, a potent and highly addictive central nervous system stimulant. *See* 21 U.S.C. 802(34); *id.* 812(c); 21 CFR 1308.12(d). Moreover, in the course of investigating methamphetamine trafficking, DEA has frequently found that the listed chemicals which are used by smaller illicit labs have been sold by convenience stores, gas stations, and other small retailers. GX 51, at 56, 59, 62, 66; GX 54, at 29–30.[6] *See also TNT*

[5] The FDA has, however, issued a notice of proposed rulemaking which would remove combination ephedrine-guaifenesin products from the OTC monograph on the grounds that they are not ''safe and effective for continued OTC availability.'' 70 FR 40232 (2005).

The parties also extensively litigated the medical appropriateness of using combination ephedrine products to treat asthma. *See* ALJ 43–48. I find it unnecessary to make any findings on this issue as until the FDA issues a final rule, combination ephedrine-guaifenesin products can be lawfully marketed for this purpose.

[6] Based on the testimony of a witness whose experience was limited to the Shenandoah, Virginia valley, the ALJ found that the street price of a gram of methamphetamine is ''between $20.00 and $50.00 per gram.'' ALJ at 48–49. Based on this, as well as evidence regarding the yield and conversion rate, the ALJ found that ''it would cost a methamphetamine cook between $50.00 and $144.00 to produce 1 gram of methamphetamine.'' ALJ at 50. The ALJ thus concluded that ''using the Respondent's product to manufacture methamphetamine makes little monetary sense.'' *Id.* at 96.

I reject the ALJ's finding regarding the street price of methamphetamine and her conclusion that using Respondent's product ''makes little monetary sense.'' *Id.* As for her findings regarding the street price of methamphetamine, I note that it is based on anecdotal evidence and limited to a small region of the State of Virginia. Respondent does not, however, limit its distribution of SLCs to this region of the country. I further note that it runs counter to the data which this Agency obtains on a periodic basis, and which show that in most of the country, methamphetamine prices are substantially higher than they are in the Shenandoah Valley. *See* U.S. Dep't of Justice, *National Illicit Drug Prices—December 2007*, 32–37 (Mar. 2008). In accordance with 5 U.S.C. 556(e), and 21 CFR 1316.59(e), I take official notice of the methamphetamine street price data contained in this publication. Moreover, the ALJ's conclusion assumes that methamphetamine addicts engage in economically rational behavior. There is, however, no evidence in the record to support this assumption. I therefore reject the ALJ's conclusion.

Continued

Distributors, 70 FR 12729, 12730 (2005) (noting testimony of Special Agent that ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores'').

Prior to the suspension of its registration, Respondent sold combination ephedrine and pseudoephedrine products under the brand names of Double Action, Mini, and Ephedrine Plus in package sizes of two, six, twelve and twenty-four count. Tr. 561, 692–93. Respondent sold these products to approximately 3,500 to 4,000 convenience stores in approximately thirty different States. *Id.* at 80–82, 558–60. Respondent does not carry any other OTC drug products. *Id.* at 552.

Respondent employs approximately 150 sales persons, who typically visit each store every other week.[7] Tr. 2046, 1290. Using its own tractor-trailers, Respondent ships products including SLCs from its Greenfield warehouse to each sales person's ''drop-off point,'' which is a unit in a commercial self-storage facility. *Id.* at 73–75. According to the testimony of Respondent's owner and CEO, Respondent was using approximately 150 to 180 drop-off points at the time the immediate suspension was served on it. *Id.* at 76. Both the driver who delivers the product to the drop-off point and the route sales person have keys to the storage unit. *Id.* While the sales persons are notified of each arriving shipment, SLCs can sit in the storage units for several days before the sales person retrieves them for delivery to the stores.[8] *Id.* at 534, 668. Moreover, according to one of Respondent's executives, the SLCs can remain on the salesperson's truck for up to nine days depending upon the demand for the product. *Id.* at 1282, 1421.

None of the drop-off points is registered with the Agency. Tr. 1284. Moreover, the units do not have separate cages for storing SLCs, *id.* at 132, and the facilities have varying degrees of external security with some having cameras and requiring access codes while others have no additional security. *Compare id.* at 131, *with id.* at 538 (former salesperson testifying that anyone could come off the road and access the door and padlock to his route storage unit).[9] Moreover, DEA Investigators could not determine the addresses of thirty-four of the drop-off points. Tr. 1196–98.[10]

In a letter dated May 5, 2004, the Diversion Group Supervisor of the Indianapolis, Indiana DEA District Office, advised Respondent that ''any storage at, and distribution from, a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law.'' [11] GX 100. Upon review of the letter, Respondent sought a declaratory judgment in Federal District Court challenging the interpretation set forth in the letter. Tr. 652–53. At no time, however, did Respondent change its practice of distributing to the drop-off points. *Id.* at 664–65. Nor did Respondent seek a review of the letter by officials at the Agency's headquarters. ALJ at 18.

The record further establishes that at the time the listed chemical products are shipped from its Greenfield, Indiana warehouse (which is its only registered location) to the drop-off points, the products have not been sold to a particular store. Tr. 2079. Indeed, the amount of SLCs to be sold to a customer is not known until the route sales person visits the store and determines how much product the store needs. *Id.* at 1282. The sales person counts the product on hand, discusses the order with the store manager, and restocks the store. *Id.* at 631; 1422.

Moreover, at the time an SLC order is placed, only the salesperson—and no one at Respondent's headquarters—knows how much the store has purchased. *Id.* at 633. The salesperson is required to enter the order information into a handheld computer which generates an invoice; this information is later transmitted back to Respondent's headquarters. *Id.* at 634. The salesperson is also required to return a paper copy of the invoice, as well as a shipping document which accompanies the delivery of the SLCs from the warehouse, to headquarters. *Id.* at 688. Under its system, while Respondent's headquarters can determine which salesperson has received product with a particular lot number, it cannot identify the specific store that obtained a particular lot number of a product. *Id.* at 1517.

Respondent's CEO testified that a store could purchase up to a case of an SLC product in each ''service cycle.'' [12] *Id.* at 101. Accordingly, most stores could purchase two cases per month of each product. Moreover, Respondent sold more than ten different SLC products. *Id.* at 623.

According to one of its executives, the company monitors the sales of each SLC product at each store throughout the week to determine whether a store ''is increasing [its] inventory more than [Respondent] expects [it] to,'' and if it is, the company contacts the salesperson to

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I also find that this witness's testimony that convenience stores are not the source of precursors in the Shenandoah Valley (ALJ at 49), to be anecdotal and contrary to the Agency's experience throughout the country. I thus give it no weight.

[7] Approximately 90% of the stores are on this schedule; the remaining stores are visited either weekly or monthly. Tr. 1290.

[8] It is undisputed that the SLCs are not shipped back to Respondent's registered location prior to their being distributed.

At the hearing, an executive of Respondent insisted that ''we are not storing product in * * * unregistered locations,'' and added: ''Now your coming back into the definition of what is storage. We're not storing the product in that location,'' referring to the drop-off points. Tr. 666–67. *See also id.* at 668 (''We're not storing or keeping or whatever words you want to try and use, product in these warehouses, against the law. We're not doing it.''). The executive acknowledged, however, that products may stay in the storage units for ''a few days.'' *Id.* at 667. I therefore find that Respondent is storing products in the self-storage units.

Respondent further asserted that its distribution system provided more security than shipping the products via such common carriers as UPS or Fed Ex. *See* Tr. 644–45. Yet an executive of Respondent acknowledged that it uses temporary drivers on a contract basis. *Id.* at 693, 697. Relatedly, Respondent's CEO offered testimony as to perceived security inadequacies at UPS, asserting that ''[p]roduct delivered by UPS could easily be stolen anywhere in the system.'' *Id.* at 157.

On cross-examination, however, Respondent's CEO admitted that he had not taken a tour of a UPS facility. *Id.* at 161. When asked when he had last ''checked into the training that UPS personnel have with regard to handling [SLCs]?,'' he answered: ''I assume they don't have any training, since they're not DEA regulated facilities.'' *Id.* at 162. The ALJ did not address the credibility of the CEO's testimony. As ultimate factfinder, I reject it as lacking foundation.

[9] There is no dispute that the security at Respondent's Greenfield warehouse is adequate. It is also undisputed that following the enactment of the CMEA, Respondent prepared a training video for its customers and supplied them with logbooks and cases for storing SLC products. Tr. 1390 & 1422; RXs 34, 47, & 48.

[10] On its list of shipments, Respondent used code numbers to indicate where products were being shipped to. Tr. 1196. Moreover, Respondent initially refused to turn over information identifying the addresses of the drop-off points for the sales routes, claiming that it was outside the scope of the warrant. *Id.* at 1197.

[11] The letter also reviewed three scenarios ''in case [Respondent was] storing List I chemical products * * * and distributing them from satellite locations, such as commercial storage units, personal residences and or delivery vehicles.'' GX 100, at 1. The first two scenarios involved sales representatives who picked up listed chemicals from a registered location either to fill a pre-placed order or a ''general order,'' and could not return the products ''to the registered location at the end of the day.'' *Id.*

The third scenario was ''a company [that] ships orders containing List I chemicals to sales representatives at remote locations.'' *Id.* at 2. The letter further explained that ''DEA considers this to be freight forwarding and at this time * * * has no provisions that would permit freight forwarding for List I chemical products.'' *Id.*

[12] With respect to the 24-tablet products, the record establishes that there were 144 packages in a case. Tr. 621. The record does not, however, establish how many packages there were in a case of the smaller size packages. *Id.* at 624.

inquire further. *Id.* at 2061–62. This executive also asserted that in this event, it would send in one of the salesperson's supervisors to visit with the sales person and determine the true inventory at a store. *Id.* Moreover, another executive claimed that he ''receive[s] a computer-generated report indicating any time that more than one case has been sold to a single retail location of a single'' product and issues a warning letter to its salespersons. *Id.* at 1431. Respondent's CEO and Owner further testified that if a customer obtained more than a case of a product, he ''would cut them off, [and] stop the sale of product to them.'' [13] Tr. 159. *See also* RX 10, at 1 (asserting that stores purchasing ''unusual quantities'' would be ''monitored over the following 4 week period,'' and that ''[i]f further unusual activity is noted,'' Respondent ''will discontinue sales of all or part of the List I products sold to the store'').

According to one of Respondent's executives, between January 17, 2007 and January 17, 2008, that there had been ''approximately 35 to 45'' violations of the one case limit, and most of the violations had occurred before July 2007, when the Agency executed the administrative warrant. *Id.* at 1433. The ALJ, however, credited the testimony of a DEA DI who reviewed Respondent's sales records for the period between January and July 2007, and found that its salespersons exceeded the one case limit 85 times. Tr. 1496–1506; GX 68.

The same executive stated that Respondent had only started issuing written warnings to its salespersons after August 2007 because of a computer ''glitch'' which had resulted in the reports not being issued as scheduled. *Id.* at 1435. Moreover, while Respondent introduced into evidence a few e-mails indicating that the company had cut off supplying 100-count bottles to several stores, Respondent did not identify a single store to which it had refused to sell ephedrine.[14] Indeed, according to its own evidence, one of the stores (BPM55), which it had previously stopped selling 100-count products to because of its excessive purchases, was allowed to purchase products with a retail value of more than $7300 a month, in the three months prior to the issuance of the suspension order. *Compare* RX 56, at 1, *with* RX 27a, at 1.

According to one of its executives, Respondent's SLC customers purchased SLCs with an average retail sales value of $640 per month, with the majority of the products containing ephedrine. *Id.* at 563–64. Moreover, according to one of Respondent's exhibits, in the three months prior to the issuance of the suspension order, it distributed listed chemicals products with an average monthly retail sales value greater than $2000 to approximately 120 of its customers. RX 27A. Respondent also distributed listed chemical products with an average monthly retail sales value in excess of $3000 to thirty-four customers, and product with average monthly retail sale value greater than $4000 to nine customers. *Id.* Finally, Respondent distributed to its two largest customers, products with an average monthly retail sales value of $5056 and $7314 respectively. *Id.*

At the hearing, the Government put forward expert testimony to the effect that the expected sales range of ephedrine products at convenience stores to meet legitimate demand was $14.39 per month. GX 25, at 8. In his declaration, the Government's expert stated that U.S. Economic Census data show that only about 31.5% of all convenience stores (45,077 stores) carry non-prescription drug products. GX 99, at 7. According to his declaration, the Government's expert then applied ''these statistics'' to the National Association of Convenience Stores 2007 Survey revenue data which show that convenience stores sold a total of $292,000,000 of cough and cold remedies during 2006, to calculate the annual and monthly average sale of cough and cold products at a convenience store. *Id.* According to the Government's expert, stores carrying the HBC line had average annual sales of all cough and cold products of $4,080.18, and average monthly sales of $340.01. *Id.*; *see also id.* at Table 2.

The Government's expert did not explain, however, why he used the total number of stores carrying the HBC line [15] (71,565 stores) rather than the smaller number of stores that he had determined carried non-prescription drug products (45,077 stores). *See id.* at Table 2. Moreover, the Government did not rebut the testimony of Respondent's expert that because of legislation in twelve States, convenience stores can no longer sell ephedrine products and that the stores in these States comprise 23% of the nation's convenience stores. RX 59, at 10. This suggests that at most, 34,709 convenience stores nationwide carry ephedrine products. *Id.*[16]

Next, the Government's expert determined the percentage of cough and cold remedies comprised of ephedrine products. GX 99, at 8. According to the Government's expert, ''[t]his factor was derived from a tabulation of MRI data showing asthma remedy usage by retail channel (in this case, convenience stores).'' *Id.* Based on this data, which was included at Table 1, the Government's expert concluded that ephedrine products constitute 8.36% of cough and cold remedies sold at convenience stores. *Id.* Multiplying this figure times the average monthly total sales of cough and cold products, the Government's expert concluded that the average monthly sale of all ephedrine products at convenience stores selling the products was $28.43.[17] *Id.*

Respondent's expert stated, however, that the MRI Survey (which is a survey of 50,000 consumers) does not provide sufficient information to support the Government's expert's figure that ephedrine products constitute 8.36% of cough and cold remedies sold at convenience stores. RX 59, at 11. Respondent's expert noted that the MRI Survey (which was included as an attachment to RX 59) ''reports absolutely no information about any ephedrine products,'' and ''reports absolutely no information on whether consumers bought either an asthma remedy or a cough and cold remedy from convenience stores.'' *Id.* (emphasis deleted).

[13] While the ALJ credited the CEO's testimony, the e-mails discussed in note 14 below, show otherwise. *See, e.g.*, RX 56, at 3. Moreover, Respondent did not identify a single store which it had refused to sell SLCs to.

[14] The record contains several e-mails indicating that Respondent directed its employees to not sell 100 count ephedrine to several stores. *See* RX 56. While the e-mails expressed concerns about the excessiveness of these stores' sales of ephedrine products, notably, Respondent did not cut off all sales of the products to any of the stores. *See id.* Moreover, while it restricted its sales ''to a maximum of [one case] every 2 weeks'' and prohibited the sale of 100 count ephedrine to store number BPM55, this store was its leading SLC customer in the three months prior to the issuance of the suspension order, during which it purchased products with an average of retail value of $7317.77 per month. *Compare* RX 56, at 1, *with* RX 27A, at 1.

[15] The HBC line includes analgesics, stomach remedies, vitamins, other OTC drugs, grooming aids, feminine hygiene, family planning, baby care, skin care, cosmetics, and some other unspecified products.

[16] Respondent's expert also pointed out that some convenience stores that carry non-prescription drug products may not sell any ephedrine. RX 59, at 10.

[17] As part of its case, the Government entered into evidence a declaration prepared by its expert in another matter. *See* GX 25. In this document, the expert stated that he had also looked at data which included ''cumulated observed transactions,'' such as scanner data obtained by Information Resources, Inc. *Id.* at 7. The Government's expert also testified that in preparing GX 25, he had reviewed scanner data to determine ''the proportion of the nonprescription drug category that included preparations for the treatment of asthma containing ephedrine.'' Tr. 313 & 500. However, in his rebuttal declaration, the Government's expert made no mention of having used scanner data. *See* GX 99.

Respondent's expert further opined that the MRI Survey asks three questions which ''are inadequate to form an estimate'' of the percentage of cough and cold remedies constituting ephedrine. RX 59, at 11. The first question is: ''How many times in'' various time periods has the person used one of numerous products? *See Survey of the American Consumer* 2–106. While the survey includes a list of non-prescription cold, sinus, and allergy remedies, none of the products listed contain ephedrine. *Survey* at 12. Nor does it appear that an ephedrine product is listed anywhere in the survey.

As for the remaining two questions, the survey asks whether a person has had asthma in the last twelve months, and whether they have used a prescription drug, a non-prescription drug, an herbal remedy, or have not treated the condition at all. *Id.* at 15. The survey does not ask any further questions regarding the use of non-prescription drugs to treat asthma.

Finally, with respect to the use of convenience stores, the survey asks only whether the consumer has purchased a non-prescription/OTC drug at a convenience store in the last 30 days. *Id.* at 43. Again, the survey does not inquire further as to what type of drug the consumer may have purchased at a convenience store. The Government's expert did not explain how the data obtained in the answers to these questions supported his conclusion that ephedrine products constitute 8.36% of the cough and cold remedies purchased at convenience stores.[18]

The Government's expert further stated that he used ''[a]nother MRI tabulation showing the route of the drug (powder, tablet, liquid, mist, skin patch, etc., etc.), [which] enabled the estimate to be further adjusted to reflect tablets only * * * resulting in the final estimate of $14.78.'' *Id.* The Government's expert thus concluded that 52% of ephedrine users use tablets rather than inhalers, *id.* at Table 2; multiplying this figure times the average monthly sales of $28.43, the expert concluded that the average monthly sale of tablet-form ephedrine products at convenience stores was $14.78. *Id.* at 8.[19]

The MRI survey asks, however, only about the mode of administration with respect to cold, sinus and allergy remedies and not asthma remedies. *Survey*, at 12. Here again, it is unclear why this data provides a reliable basis for estimating the percentage of asthma sufferers who use tablets versus inhalers.

I thus agree with the ALJ that the Government has not proved by substantial evidence that the monthly expected retail sales value of ephedrine products at convenience stores to meet legitimate demand is $14.39.[20] On the other hand, it is undisputed that no ephedrine product ranks in the top 200 of over-the-counter and health-and-beauty care products which are sold in drug stores, supermarkets, and mass merchandisers. *See* GX 99, at 4. It is also undisputed that approximately 97% of the sales of non-prescription drugs occurs at pharmacies, supermarkets, warehouse clubs, department stores, electronic shopping/mail order houses, and other general merchandise stores. GX 25A, at C2. Moreover, convenience stores (both those with and without gasoline) account for approximately 1.14% of the total commerce in non-prescription drugs. *Id.* The Government, however, produced no evidence as to the annual sales of combination ephedrine products such as Primatene Tablets and Bronkaid, which are sold at pharmacies, supermarkets, and other large volume retailers of non-prescription drugs.

Evidence of Diversion

In September 2002, DMD Pharmaceuticals, a supplier to Respondent, shipped it an entire lot of sixty-count bottles of a combination ephedrine (25 mg.) product.[21] Tr. 1079. Two months later, twenty-two bottles of this lot were found at an illicit methamphetamine laboratory in Thompson, Connecticut. *Id.* at 1077. DEA subsequently issued a warning letter to DMD. *Id.* at 1077–78.

Several months later, while completing a previously-commenced inspection of Respondent, a DI discussed the matter with two of its executives. *Id.* at 1082–83. While the executives provided the DI with the names of two salespersons whose territory included or was near the part of Connecticut where the lab was found, they could not identify which specific stores had obtained the ephedrine. *Id.* at 1084.

As part of the investigation that gave rise to this proceeding, DIs based in four States visited a number of Respondent's customers. At a Roadrunner Market in Bristol, Tennessee, a DI testified that during the ''time period of July 23rd through August 23rd'' of 2007, three customers had purchased quantities that far exceeded nine grams.[22] Tr. 730–733. While 439 gel caps in 25 mg. strength is the dosage form equivalent to the nine gram limit, M.W. had bought 56 boxes totaling 1,344 gel caps or approximately 27 grams. GX 46. During the same period, C.M. purchased 23 boxes totaling 552 gel caps (approximately 11.3 grams), and E.B. purchased 52 boxes totaling 1,248 gel caps or approximately 25.6 grams. *Id.* The DI also found other evidence of repetitive purchasing patterns at the stores, but the logbooks were missing information such as the number of dosage units and/or strength of the product. *See* GX 80.

A different DI visited the Smoker Friendly No. 4 Store in Little Falls, New York, and obtained the logbooks. Tr. 785–86, 791–92. The logbooks showed that between July 27, 2007, and August

[18] Respondent's expert noted that she was informed by its executives that ephedrine products constituted 60% of its customers' SLC sales. RX 59, at 12. Even if this is an accurate figure with respect to its customers, Respondent does not allow them to purchase SLCs from other suppliers, Tr. 626–27, and it does not sell any nationally-branded OTC pseudoephedrine remedies such as Sudafed or Claritin D. The figure is thus based on a biased sample.

[19] Because the average retail price for a box of the two leading brands of ephedrine was $7.19, the Government's expert then further reduced the average monthly sales figure from $14.78 to $14.39 ''to reflect the purchase of exactly two boxes of 24 count ephedrine tablets.'' *Id.* at 9.

[20] The Government offered evidence regarding visits or telephone contacts made by various Diversion Investigators (DIs) to eighteen pharmacies which were apparently located near some of Respondent's customers. *See* ALJ Dec. at 23–33. At least half the pharmacies did not carry any ephedrine products. *See id.* As for the remaining pharmacies, the Government produced evidence as to their sales levels of ephedrine products with respect to only four of the pharmacies. This evidence showed that the pharmacies were selling minimal quantities of tablet-form ephedrine products, with the most that any store sold being 71 boxes in a four-and-a-half month period. *See, e.g.*, GXs 26, 27, 28 & 29.

The Government did not establish that it used a statistically valid sampling technique in choosing the pharmacies the DIs interviewed. The evidence thus amounts to nothing more than a collection of anecdotes. To the extent the evidence is offered to show that there is little demand at pharmacies for these products, it is of limited probative value.

[21] According to the testimony of a DI, DEA issued DMD a warning letter. Tr. 1078. Upon receipt of the letter, DMD's compliance manager told the DI that he would look into to whom the product was shipped. *Id.* Subsequently, the DI received a phone call from DMD's compliance manager and owner informing her that ''that entire lot had been sold to'' Respondent in September 2002. *Id.* at 1079. The ALJ credited this testimony, *see* ALJ at 13, as do I.

[22] It is noted that the time period which was reviewed exceeded thirty days. Even assuming that these persons did not violate Federal law in purchasing these products, given the dosing instruction for these products (one tablet every four hours and no more than six tablets every twenty-four hours), their purchases are not consistent with the use of the products to treat asthma. *See, e.g.*, RX 9, at 1. Moreover, the ''Drug Facts'' warning label for Respondent's Double Action Ephedrine (25/200 mg.) product further advises to ''Stop use and ask a doctor if * * * cough persists for more than 1 week.'' *Id.*

27, 2007, four persons had purchased more than nine grams. K.S. bought 984 tablets of ephedrine 25 mg. (more than 20 grams), and A.P. bought 768 tablets of ephedrine 25 mg. (approximately 15.7 grams). GX 45. Moreover, Richard and Robert R., who had the same last name and used the same address, respectively purchased 600 and 696 tablets of ephedrine 25 mg. *Id.* These purchases amounted to 12.3 and 14.25 grams. *Id.*

Another DI visited the Mason of New York convenience store of Jamestown, New York, and obtained the logbook. Tr. 1484. The logbook entries were frequently missing information as to the strength of the ephedrine tablets that had been purchased. Nonetheless, the logbook showed that there were five individuals who, even if they had purchased only 12.5 mg. ephedrine, had nonetheless purchased more than nine grams during the period between July 21 and August 21, 2007. More specifically, M.M. purchased 1,368 tablets (14 grams),[23] A.J. purchased 1,014 tablets (10.4 grams), J.B. purchased 1,548 tablets (15.9 grams), J.H. purchased 1,068 tablets (10.9 grams), and R.B. purchased 1,002 tablets (10.3 grams).[24] GX 49.

A Pennsylvania-based DI likewise found evidence of purchases that, while technically not in violation of the CMEA, raised a strong suspicion that the ephedrine was being diverted. For example, at the CoGo of Somerset, Pennsylvania, a DI found that S.M. had bought 384 dosage units between August 16 and 23, 2007. GX 75. At 12.5 mg. strength, this amounted to 3.9 grams. This individual had also bought three twenty-four count boxes on three consecutive days.[25] *Id.* Moreover, another DI visited a CoGos in Midland, Pennsylvania, and found evidence that a person had bought 620 dosage units of 12.5 mg. between May 1 and May 31, 2007, and an additional 636 dosage units between June 1 and June 15, 2007. Tr. 1486; GX 41.

[23] A person named Chris M. (with the same last name and address as M.M.) purchased an additional 360 tablets. GX 49.

[24] All of these calculations assume that these persons bought 12.5 mg. tablets; if they bought 25 mg., then the amount of ephedrine was double. Moreover, the DI found that four other persons had purchased quantities which would exceed nine grams if the strength of the tablets was 25 mg.

[25] At two stores, the DI did not find any evidence of purchases in excess of the limit and was told by the managers that the products were primarily purchased by hospital workers and truck drivers who used them to stay awake on their jobs. Tr. 872–73; 886–87.

The Allegation That Respondent Distributed Listed Chemicals to Uncertified Retailers

Effective September 30, 2006, the CMEA prohibited a retailer from selling schedule listed chemical products unless the retailer had self-certified to the Attorney General that all ''individuals who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payment for the products * * * have * * * undergone training provided by the seller to ensure that the individuals understand the requirements that apply'' to the sale of the products. 21 U.S.C. 830(e)(1)(VII). As stated above, the Government alleged that between January 1, 2007, and July 9, 2007, Respondent made 284 distributions of listed chemical products to thirty-five retailers who were not self-certified.

As support for the allegation, a DEA DI testified that using a document supplied by Respondent which listed the customers by code number, store name and address, she conducted a spot check to see if the stores were listed in the Agency's database of stores that had become certified. Tr. 1213–19. The DI further testified that the results of her inquiry were reported in a thirteen page document, which listed the distributions by Respondent's store code number, the date, Respondent's product code, and quantity. *Id.* at 1218, *see also* GX 40 (listing stores and transactions).

At the hearing, Respondent produced numerous documents that refuted the allegation. For example, the Government listed twenty-five Speedway stores that were located in Indiana and Kentucky which had obtained SLCs from Respondent between April 10 and July 9, 2007. GX 40, at 3, 6 & 7. Respondent, however, introduced into evidence, a letter dated April 3, 2007 from an executive of Speedway Super America to DEA's registration unit submitting a CD–Rom with the certification data for the company's stores in Indiana and Kentucky. RX 57. Respondent also submitted copies of each store's certification. *See* RX 57A. While each of the certifications was dated July 5, 2007, the Government did not rebut Respondent's evidence that the Agency considers a chain retailer who submits information on a CD–Rom to be self-certified on the date the information is received by the Agency. Tr. 1335–36.

At most, the evidence suggests that Respondent made a single distribution to a single store before it obtained its certification. *Compare* GX 40, at 14, *with* RX 57, at 18. According to these exhibits, Respondent distributed a listed chemical product on January 18, 2007, to an independent convenience store located in Centreville, Virginia, prior to the store obtaining certification on March 8, 2007.[26]

The evidence did show, however, several instances in which Respondent's records contained erroneous information. For example, Respondent's records listed the address of store XTM7480 as 1451 Dorsey Road, Hanover, Maryland. GX 39, at 100. The store's DEA Certificate states, however, that its address is 7500 Ridge Road, Hanover, MD. RX 57, at 14. Respondent's records likewise listed the address of store XTM7520 as 7300 Washington Blvd., Dorsey, MD. GX 39, at 100. According to its DEA certificate, the store's address was 7300 Washington Blvd, Elkridge, MD. RX 57, at 15. Also, Respondent's record listed the address of store MTO102 as 995 Old Airport Road, Bristol, TN. GX 39, at 33. The store's DEA certificate, however, gives its address as 1001 Airport Road, Bristol, Va. RX 57, at 16.[27]

The Allegations That Respondent Distributed Products in Forms That Could Not Be Lawfully Sold Under the CMEA and State Laws

Effective April 9, 2006, the CMEA prohibited a retailer from selling a listed chemical ''product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs * * * containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches.'' 21 U.S.C. 830(d)(2). The Government alleged that subsequent to February 1, 2007, Respondent distributed 24-count bottles of listed chemical product to retailers on three occasions.

In support of this allegation, the Government introduced a document which lists three distributions of Respondent's product # 17902, Mini 2 Way 25 mg. gel caps in 24 count bottles, to three stores (PTR3295, PTR3438, and PTR3973).[28] *See* GX 66 & 37. A DI testified that the three transactions were found in Respondent's sales records. Tr.

[26] The store's certification shows that it was completed online at DEA's self-certification Web page. RX 57, at 18.

[27] Likewise, Respondent's records list the address for store BGP1 as 1699 N. Dixie Hwy, Monroe Michigan. GX 39. The store's DEA certificate gives its address as 1488 N. Dixie Hwy., Monroe, Michigan. RX 57, at 21.

[28] According to Respondent's sales records, two of the distributions (to stores PTR3295 and PTR3438) occurred on February 7, 2007; the other distribution (to store PTR3973) occurred on April 23, 2007. GX 66, Tr. 1442–43.

1442–45. According to Respondent's customer list, each of the stores was owned by The Pantry chain. *See* GX 39.

Respondent's record of shipments showed, however, that the product had not been shipped after January 2006. RX 40, at 152. Moreover, Respondent presented e-mail correspondence between it and an employee of The Pantry. More specifically, Respondent requested that The Pantry check its scanner data to determine whether it had sold the bottled product at the three stores after February 1, 2007. RX 46, at 2–3. In an e-mail, a Pantry employee reported that she had checked the item number for the three stores ''from Feb. 2007-Feb. 2008 and [that] there was no movement at any of the three locations for this item.'' RX 46, at 1.[29] Based on the totality of the evidence, I find that the Government has not proved this allegation.

The Government also alleged that Respondent distributed tablet-form products to retailers in Kentucky and North Carolina, after these States prohibited the sale of non-liquid products other than in gel-cap form at establishments that are not pharmacies. In support of the allegation, the Government introduced a document which listed four distributions of Respondent's product # 017550, Ephedrine Plus Blister 24 Count. *See* GX 37 & 65. Three of the distributions were made to three stores owned by Circle K Midwest which were located in Kentucky (CKM 3212, CKM 3247, and CKM 3248); the other store was owned by The Pantry and located in North Carolina (PTR3972). *See* GX 39, at 10, 11 & 65. According to Respondent's records, the distributions occurred on March 27 and 28, and July 9, 2007.

An executive of Respondent testified that its records pertaining to the four distributions were erroneous. Tr. 1347–50. Moreover, Respondent's records did not show any shipments of this product after December 26, 2005. RX 40, at 159. Finally, in an e-mail, an employee of The Pantry reported that ''there was no movement'' of the product at store number 3972. RX 46, at 1.[30] Because the ALJ found credible Respondent's explanation and did not produce sufficient evidence to reject this finding, I find that Government has proved only that Respondent's records were erroneous and that it did not violate North Carolina or Kentucky law.

The DEA Audits

On July 9, 2007, as part of an administrative inspection of its registered location, DEA Investigators took a physical count of Respondent's listed chemical products then on hand. Tr. 1163. The DIs also obtained an initial inventory dated December 25, 2005, from Respondent's records. *Id.*; see GX 4. Both the beginning and ending inventories were certified as correct by Ryan Polk, Respondent's Chief Financial Officer. GX 4. Pursuant to an agreement with the DIs, products which were stored in the returns portion of Respondent's storage cage which included out-of-date products, broken blister packs, and single loose pills were not counted. Tr. 1494–95. The products had not, however, been logged back into Respondent's records. *Id.*

DEA Investigators audited twenty different products by adding Respondent's receipts (including returns, Tr. 1182) to the beginning inventory (GX 34)[31] and comparing this figure with the sum of the closing inventory and Respondent's shipments to its salespersons (GX 35) and returns to its suppliers. *See* GX 4, at 3. Of further note, Respondent's list of shipments indicated that it had made three separate shipments of product # 17121 (totaling more than 2300 units[32]) to three of its salespersons on July 16, 2007, notwithstanding that this date was a week into the future. GX 35, at 29.

According to the DIs' calculations, only one of the products in which there was activity balanced,[33] two of the products had sizable shortages, and the remaining had overages. *Id.* More specifically, the DI identified Respondent's product code #17902 (Mini 2-Way 25 mg. 24 count gel cap bottles) as being short nearly 28,000 bottles. Tr. 1186. Moreover, the DI concluded that Respondent was short 32,913 units of product code # 17903 (Mini 2 Way 12.5 mg. gel cap 6 ct. blister packs). *See* GX 4, at 3.

The DI further testified that ''because we got different numbers when comparing [Respondent's] receipts versus their warehouse documentation,'' Tr. 1186, she conducted an additional audit of four products by obtaining information from Respondent's suppliers in order to verify its receipts. *Id.* at 1187. According to the DI, for these four products, there were substantial differences between the quantities that were reported by the suppliers and the information provided by Respondent. *Id.* With respect to product # 17121 (Double Action 6 ct. ephedrine 25 mg. tablets), Respondent had represented that its receipts were 656,688, but according to the DI, the suppliers had claimed to have sold it only 429,024 units resulting in an overage of more than 275,000 units. Tr. 1188; GX 4, at 3. The DI also found overages in the other three products which were subject to the additional audit. GX 4, at 3. The DI further testified that she prepared an additional document which compared the receipt information provided on Respondent's printouts, the hard copy invoices of Respondent's receipts, and the quantities which the manufacturers of Respondent's products reported to the DI. Tr. 1189–90; GX 69.

According to this document, while Respondent's printout of its receipts for product #17103 (525,240 units of Double Action 12 ct. Blister 25 mg.) matched the quantity of the manufacturer's report, Respondent had no hard copy invoices. GX 69. With respect to product # 17131 (Double Action Pseudo tablets 12 mg.), Respondent's printout indicated it had received 404,184 units and the manufacturer reported that it had sold 403,248 units to Respondent. *Id.* Respondent did not, however, have any hard copy invoices for the product. *Id.* With respect to product # 17121 (Double Action 6 ct. ephedrine 25 mg.), Respondent's receipts (656,688 units) matched the number reported by the manufacturer. *Id.* Respondent, however, had hard copy invoices for only 429,024 units. *Id.*

With respect to product # 17125, Respondent's printout indicated it had received 1,011,901 units, which matched the total quantity reported by the two suppliers of this product. *Id.* Respondent, however, had invoices only

[29] Respondent's CEO attributed the data as resulting from its salesperson[s] having entered the wrong product code in their computer. Tr. 68. Another of Respondent's testified that that it had reprogrammed its computer system to prevent a salesperson from selling an item that was prohibited. *Id.* at 1404. Yet even after the reprogramming, there were several instances in which salespersons entered the codes for discontinued products. *Id.* at 1405. The same executive acknowledged that he did not know if the salespersons still had obsolete products in their storage units. *Id.*

[30] Respondent also submitted an e-mail from an employee of Circle K., which states that she checked the stores' sales going back to April 30, 2007, and that the stores had not sold the product. RX 46, at 5. The e-mail is thus not probative of whether Respondent distributed the products in violation of Kentucky law.

[31] According to the DI, the investigators ''asked to see receipts for the products audited for a time period. And we were, instead, given this three-page summary.'' Tr. 1170. Relatedly, the DI testified that while Respondent gave them a 157 page list of its shipments, the document used product codes and the Investigators had to ask several times for a document which identified the products. *Id.* at 1180–81.

[32] This product was a six-count blister pack. *See* GX 32, at 1.

[33] While two other products balanced, the computation chart indicates that there was no beginning or closing inventory of, and no activity in, these products. GX 3, at 6.

for 851,671 units. *Id.* Apparently, Respondent was also missing invoices for other products.[34] *Id.*

Respondent's CFO testified that upon being provided with a copy of the Government's audit, he proceeded to conduct his own audit. With respect to product # 17902, which the Government had concluded was short, the CFO testified that the DIs had ''excluded a transaction for 28,800 units where we sent that product back to the original manufacturer'' because in his words, it ''was an obsolete item.'' Tr. 2036; RX 36, at 4. The ALJ further found credible the CFO's testimony that he had provided this information to the DIs as part of their document request. *Id.; see also* ALJ at 42.[35] Respondent also introduced into evidence numerous documents listing inventory adjustments and data pertaining to items that had been removed to the ''obsolete inventory area'' which its CFO asserted had been excluded by the DIs in doing the audit. Tr. 2037; RX 36. As for Respondent's other product (# 17903), which the Government concluded it was short nearly 33,000 units, Respondent introduced into evidence two documents listing various inventory adjustments which it contended had not been considered by the Government and which would have greatly reduced the discrepancy. GX 36, at 2. On cross-examination, the CFO maintained that he had provided these documents no later than July 18, 2007. Tr. 2085. Notably, the Government did not rebut either the CFO's testimony that the documents had been provided or that it had failed to consider them in performing the audit.

Respondent's CFO also testified that the additional audit (performed on the four products) was flawed, asserting that with respect to two of the items (#s 17121 and 17125), the Government had ''exclude[d] a very large receipt that's on the sales record from those suppliers.'' Tr. 2038–39. With respect to product # 17121, the CFO testified that the Government had excluded ''227,664 units [that] were listed on the report as sold to'' it. *Id.* at 2039. As for product # 17125, which came from two suppliers, the CFO stated that the Government had excluded transactions totaling 160,000 units. *Id.*

While the purpose of the second audit was to obtain information from Respondent's suppliers and verify it with Respondent's reported receipts, in fact, the audit appeared to have been based on Respondent's actual invoices and not the reported figures (which appear to have been used in the first round of audits). *Compare* GX 69, *with* GX 4, at 3.[36] In his testimony, however, Respondent's CFO did not address the Government's contention that Respondent was missing various invoices of its receipts and Respondent does not cite to any specific evidence of record rebutting the allegation. *See* Tr. 2042 (CFO testified that ''I think in a couple of instances—I did not include the pages in this [exhibit RX 36], for example, Item 17121 when the Government excluded the 227,000 units.''). Accordingly, I find that Respondent was missing numerous invoices documenting its purchases from its suppliers.

Respondent's Post-Suspension Conduct

Following the issuance of the suspension order, Respondent engaged in discussions with BDI, Inc., one of its suppliers, under which Respondent proposed to have its sales persons take orders for SLCs, which would then be sent back to its headquarters and forwarded on to BDI, which would fill the orders by shipping them to its customer by UPS. GX 48; Tr. 2401–02. According to a February 8, 2008 letter which was signed by its CEO, under the scheme, Respondent's sales persons would ''still do all reordering and stocking of the merchandise as we have in the past,'' and when a shipment arrived at a customer, ''the manager [would] have the choice of stocking the OTC cabinet or holding it for our sales person.'' GX 48. The letter further stated: ''This basically keeps the business the same. The only difference is a UPS box. All invoices are from Novelty, Inc.'' *Id.*

Respondent's Vice President of Product justified the scheme, reasoning that under his ''definition of sales, we're not involved in the distribution of the product. But our sales people are in that store functioning as an agent.'' Tr. 2402.

Because BDI refused to participate, the scheme ''was never implemented.'' *Id.* at 2403. However, at the hearing, Respondent's VP testified that the scheme was ''[s]omething that we're still continuing to explore.'' *Id.*

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical ''may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render [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 (DC Cir. 2005).

In this matter, I have considered all of the statutory factors.[37] While I have found that several of the Government's allegations have not been proved, I nonetheless conclude that Respondent does not maintain effective controls against diversion and that its

[34] The DI also testified that there were thirty-four sales routes for which Respondent did not provide address information indicating where its products were being shipped to. Tr. 1197–98, GX 67.

[35] The ALJ noted that this document shows a return of 57,600. ALJ at 43. That figure appears, however, to be the amount of the credit Respondent was entitled to. RX 36, at 4.

[36] For example, both Respondent and the manufacturer agreed that Respondent had obtained 656,688 packets of product # 17121, but Respondent's invoices only added up to 429,024 units. GX 69. In the first audit, the Government used the 656,688 figure, and in the second audit, which was supposedly based on the information it obtained from the manufacturer, it used the 429,024 figure. *See* GX 4, at 3. It did the same thing with respect to product # 17125, using the 1,011,901 figure (which Respondent and the two manufacturers agreed with) in the first audit. *Id.* Again, in the second audit, it used the 851,671 figure, the figure that was based on the actual invoices produced by Respondent. *Id.; see also* GX 4, at 3.

[37] I note that there is no evidence that Respondent has been convicted of an offense related to controlled substances or listed chemicals.

distribution practices and recordkeeping did not comply with Federal law. Moreover, while I have carefully considered the ALJ's findings regarding Respondent's willingness to comply with Federal law and her recommendation that I continue its registration with conditions, I conclude that on balance, the ALJ did not give sufficient weight to several factors including Respondent's failure to enforce its own policies, its sustained conduct in continuing to distribute out of unregistered storage facilities even after being advised that its practice was illegal, and its attempt to circumvent the suspension order. Accordingly, Respondent's registration will be revoked.

Factor One—Maintenance of Effective Controls Against Diversion

Under agency decisions, this factor encompasses a variety of considerations. *Holloway Distributing, Inc.*, 72 FR 42118, 42123 (2007). These include the adequacy of the registrant's/applicant's security arrangements, the adequacy of its recordkeeping and reporting, its distribution practices, and the occurrence of diversion. *See id.; see also Rick's Picks*, *L.L.C.*, 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).

In evaluating a registrant's security controls and procedures, DEA regulations direct that the Agency consider the following eight factors:

(1) The type, form, and quantity of List I chemicals handled;

(2) The location of the premises and the relationship such location bears on the security needs;

(3) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(4) The availability of electronic detection and alarm systems;

(5) The extent of unsupervised public access to the facility;

(6) The adequacy of supervision over employees having access to List I chemicals;

(7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored;

(8) The 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.[38]

It is undisputed that Respondent maintains adequate physical security of the list I chemicals which it stores at its registered location. The record further establishes, however, that Respondent then ships the SLCs to between 150 to 180 self-storage units throughout the country, where the products may be kept for up to several days at a time before the route sales persons retrieve them. Tr. 534 & 667–68.

As found above, Respondent disputes that this practice constitutes storage. *See* Tr. 666 (Executive testifying that: ''That's a nonsense question. Now you're coming back into the definition of what is storage. We're not storing the product in that location.''); *id.* at 672 (''We are not storing or keeping or whatever words you want to try and use, product in these warehouses, against the law.''). Likewise, in its brief, Respondent engages in the tortured argument that it does not store products in the self-storage units because ''[t]he definition of 'store' focuses on future, not present use,'' and it uses the units only for what it terms is an ''immediate'' and not a ''future use.'' Resp. Br. 99.

This argument begs the question of why Respondent needs to rent storage units if not to store products in them. Moreover, the record is clear that the products are typically not immediately transferred from the delivery truck to the route salesperson and that products may remain in the storage unit for up to several days before the route sales person retrieves them. Respondent is therefore using the self-storage areas for storage.

Moreover, putting aside momentarily the issue of whether these storage units must be registered, it is unlikely that they could meet the security requirements of this Agency. Indeed, DEA has previously rejected applications of entities that sought to store SLCs in public storage facilities on the ground that they present an unacceptable risk of diversion. *See Stephen J. Heldman*, 72 FR 4032, 4034 (2007); *see also Sujak Distributors*, 71 FR 50102, 50104 (2006).

In these decisions, I have noted a variety of security concerns which are raised by these facilities including the inadequacy of their construction, the lack of alarm systems, the lack of 24 hour on-site monitoring, the ability of unauthorized persons to gain access to the facility and the storage units, and the fact that the tenant does not control what other tenants the landlord rents to. *See, e.g., Sujak*, 71 FR at 50104. Here, for example, a former salesperson for Respondent testified that his storage unit was in a facility which lacked a secure perimeter and that anyone could come off the road and gain access to the door of his unit. Tr. 538. It also is undisputed that the storage units did not have separate cages within them for securing the products. *Id.* at 133. Finally, to this day, the Agency does not know where thirty-four of the storage units are located. Tr. 1196–98. Respondent's use of these storage facilities thus does not provide adequate controls against diversion and provides reason alone to support the finding that its continued registration ''is inconsistent with the public interest.'' 21 U.S.C. 823(h).

The record identified a further serious deficiency in the security of Respondent's distribution practices. As found above, SLCs may remain on a salesperson's truck for up to nine days before being delivered to a store. This practice presents a serious security concern because of the risk that a thief can steal the vehicle's cargo. Indeed, by stealing the entire vehicle with its cargo—an act which takes but seconds to perform—a thief does not have to spend time offloading the SLCs. *See McBride Marketing*, 71 FR 35710, 35711 (2006). Moreover, the risk posed by Respondent's distribution practice is exacerbated by the extensive time period during which the products remain on its trucks.

Nor are these security concerns the only manner in which Respondent fails to maintain effective controls against diversion. The record also supports the conclusion that Respondent has serious recordkeeping deficiencies.

According to the manufacturer's sales journal, AAA Pharmaceuticals made three shipments of product # 17121 to Respondent: (1) 227,664 dosage units on August 11, 2006; (2) 228,264 dosage units on September 1, 2006; and (3) 200,760 dosage units on November 14, 2006. *See* GX 32 at 7, 8 & 11. Each of these shipments was also a ''regulated transaction'' as each exceeded the 1,000 gram threshold. 21 CFR 1310.04(f)(1)(ii). Respondent was thus required to keep a record of the transaction ''for 2 years after the date of the transaction.'' *Id.* 1310.04(a). Yet Respondent was missing an invoice for the August 11, 2006 shipment of 227,666 units, GX 69, and the computer-generated records which it provided to the Agency pursuant to the warrant did not comply with Federal law and Agency regulations because they were missing required information such as the form of packaging and the method of transfer. *Compare* GX 34,

[38] Under DEA regulations, ''[a]ny registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the Special Agent in Charge in the region in which the security controls and procedures will be used, or to the Chemical Operations Section Office of Diversion Control'' at DEA Headquarters. 21 CFR 1309.71(c).

with 21 U.S.C. 830(a)(2) and 21 CFR 1310.06(a).

With respect to product number 17103, Respondent acquired more than 525,000 units in seven different shipments between March 29, 2006, and April 19, 2006. *See* GX 3 at 2–5.[39] Here again, Respondent engaged in multiple regulated transactions and was required to keep records of them. *See* 21 U.S.C. 802(39); 21 U.S.C. 1310.04(f) (threshold for regulations transaction is based on ''the cumulative amount for multiple transactions within a calendar month''). Yet it had no invoices for any of the shipments, GX 69, and the computer-generated records it provided to the Agency likewise did not comply with the regulations.[40] Respondent was also missing invoices documenting its purchases of other products. *See id.* Respondent's failure to maintain adequate records for the regulated transactions it engaged in constitutes not only a violation of Federal law, it also demonstrates that its systems for monitoring the receipt of SLCs are inadequate.

Respondent's systems for monitoring the distribution of its products are also deficient. First, Respondent's recordkeeping is deficient in various ways. According to the shipping records which Respondent provided to the DIs on July 9, 2007, it shipped more than 2300 packages of product # 17121 to three different salespersons on July 16, 2007, even though the date listed was a week into the future.

The Government also identified several instances in which Respondent's records indicated that it had distributed products that could not be lawfully sold under either the CMEA or the laws of Kentucky and North Carolina. While I have credited Respondent's evidence that the distributions did not occur, the evidence nonetheless points to further inadequacies in Respondent's recordkeeping and systems for monitoring the distribution of SLCs.[41] Moreover, Respondent's records contained a variety of errors related to the addresses of its customers including the wrong street address, and in one case, the wrong state.

Second, Respondent's procedures for monitoring the distribution of its products are deficient. The record establishes that the placement of an order and the delivery of the products occur simultaneously, and at the time, only the salesperson knows how much the store has purchased. Tr. 633. While Respondent asserted that it monitors its sales of SLC and conducts an inquiry if a store has acquired more inventory than is expected, and that another report is prepared which lists instances in which more than one case has been sold per product during a transaction, these procedures are wholly deficient to protect against the diversion of SLCs. Moreover, as the evidence with respect to the 2002 incident in which Respondent's products were found at a meth. lab shows, under its distribution model, it can not identify which stores receive a particular product. Tr. 1517.

Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes. *See* DEA, *Chemical Handler's Manual* 21 (2002).[42] Respondent's procedure of post-transaction review is incompatible with its obligation to identify and forgo suspicious transactions.

Respondent further maintains that its imposition of its one case, per product, per service cycle limit, and its practice of issuing warning letters to salespersons who sell over the limit, demonstrates that it maintains effective controls against diversion. However, the credited testimony establishes that between January and July 2007, Respondent's sales force violated its case limit policy some 85 times. ALJ at 12. Moreover, one of Respondent's senior executives testified that it had only started issuing written warnings in August 2007, which, of course, was after the administrative inspection. Furthermore, Respondent's policy is a meaningless measure because it sells ten different products and most stores are serviced every two weeks.

The inadequacy of Respondent's control measures is further demonstrated by its own exhibit showing its sales of SLCs in the three months prior to the issuance of the suspension order. As found above, Respondent's CEO testified that its average customer sold SLCs with a retail value of $640 per month. Tr. 563–64. Yet Respondent's evidence shows that during this period, it had sold SLCs with an average monthly retail value of more than $2000 (more than three times its average monthly sale) to approximately 120 of its customers, and SLCs with an average monthly retail value of more than $3000 (4.68 times its average monthly sales) to thirty-four of its customers. RX 27A. Moreover, Respondent sold SLCs with an average monthly retail sales value greater than $4000 to nine customers. *Id.* One of these customers was purchasing SLCs with an average monthly retail sales value of $5056—approximately eight times its average customer's purchase. *Id.* Finally, its largest customer (Store # BPM55) was purchasing SLCs with an average monthly retail sale value of $7314—more than eleven times its average customer's purchase—in the three months prior to the issuance of the suspension order.

Moreover, the record establishes that Respondent had previously determined that store BPM55 was purchasing excessive quantities. RX 56. Yet notwithstanding this store's history, Respondent allowed it to purchase quantities that dwarfed that of its average customer. Furthermore, upon reviewing this store's logbook for the period July 21 through August 21, 2007, at least five individuals had purchased in excess of nine grams within this period. These customers purchased quantities which far exceeded the recommended dosing for the product's use as an asthma treatment[43] and are consistent with diversion.[44]

[39] On March 29, 2006, AAA shipped Respondent 15,984 and 114,480 units of product number 17103; a dosage unit of this product contained 25 mg. of ephedrine hcl. GX 32 at 2–3. This was followed by a shipment on April 14, 2006 of 113,856 units; a shipment on April 17, 2006 of 113, 472 units; and three shipments on April 18, 2006 which totaled 167,328 units. *See id.*

[40] Here again, there were multiple transactions that fell within the definition of a regulated transaction.

[41] I acknowledge the testimony of Respondent's executives that the errors were caused by its salespersons' erroneous entry of products codes into their computers, and that the software has since been reprogrammed.

[42] Under the Agency's policy, this manual was provided to all list I chemical distributors at various inspections. It is also available through the Agency's Web site.

[43] These five customers had purchased between 1,002 and 1,548 tablets. In contrast, Respondent's recommended dosing for its 12.5 mg product was ''2 tablets every 4 hours as needed, not to exceed 12 tablets in 24 hours,'' and to ''stop use'' and see a doctor if ''cough lasts more than 7 days.'' RX 9, at 3.

I acknowledge that Respondent cannot review the logbooks. A registrant cannot, however, ignore other evidence which is indicative of diversion.

[44] At the hearing, Respondent's Expert testified that BPM55 is an outlier and that it would not be appropriate to draw ''a conclusion about [Respondent's] customers based on relying on the . . . highest seller.'' Tr. 1722. Contrary to the understanding of Respondent's Expert, in evaluating the effectiveness of an entity's diversion controls, there are no free passes. Excessive sales to a single store are sufficient by themselves to support the conclusion that the registrant does not maintain effective controls against diversion. Moreover, as explained above, BPM55 had a history of excessive sales and had previously come to the attention of Respondent. Yet Respondent continued

Continued

Contrary to Respondent's understanding, while proof that a distributor is selling quantities in excess of the national monthly average for sales of SLCs by convenience stores would be highly probative of the distributor's lack of effective controls against diversion, it is not the sole measure for evaluating the effectiveness of those controls. More specifically, a registrant cannot ignore evidence that some of its customers are purchasing quantities that greatly exceed what its typical customer buys from it. Significantly, Respondent introduced this evidence into the record. Although in some instances there may be a plausible explanation for the disparity that does not involve diversion, Respondent offered no explanation that was specific to any store for why it was selling in such quantities.[45]

Moreover, while Respondent's CEO testified that he would cut off a customer who purchased more than a case of a product, Respondent offered no evidence that it has ever refused to sell to a customer because the customer was purchasing excessive amounts of products. Indeed, Respondent's continued sales to BPM55, at a rate that was more than eleven times what its average customer was buying, amply demonstrates that its purported written policy of monitoring those stores which purchased ''unusual quantities,'' and ''[i]f further unusual activity is noted * * *discontinu[ing] sales,'' RX 10, at 1; is a sham.

I therefore conclude that Respondent does not maintain effective controls against diversion. Given the variety of ways in which Respondent's controls are deficient, this factor strongly supports the conclusion that Respondent's continued registration ''is inconsistent with the public interest.'' 21 U.S.C. 823(h).

Factor Two—Respondent's Compliance With Applicable Laws

The Government further argues that Respondent failed to comply with Federal law and DEA regulations by distributing SLCs from the self-storage units because none of the units were registered. *See* Gov. Exceptions 1–6. The ALJ, while noting that the facts surrounding Respondent's use of the self-storage units were not in dispute, declined to address the statutory issue, reasoning that because there was then litigation pending in the U.S. District Court, the Court, and not this proceeding, is the proper forum for resolving the dispute. ALJ at 91 n.38.[46] I conclude, however, that there is no reason for the Agency to not address this issue which involves a fundamental question as to the scope of the CSA's registration requirements.[47]

Under Federal law, ''[e]very person who * * * distributes any * * * list I chemical * * * shall obtain annually a registration issued by the Attorney General.'' 21 U.S.C. 822(a)(1). ''Persons registered by the Attorney General * * * to distribute * * * list I chemicals are authorized to possess [and] distribute * * * such * * * chemicals * * * to the extent authorized by their registration and in conformity with the other provisions of'' the CSA. *Id.* § 822(b). The Act further provides that ''[a] separate registration shall be required at each principal place of business * * * where the applicant * * * distributes list I chemicals.'' *Id.* § 822(e); *see also* 21 CFR 1309.23(a) (''A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person.'').

With respect to SLC distributors, DEA has created by regulation two limited exceptions to the requirement that each principal place of business be registered. The first is for ''[a] warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered[.]'' 21 CFR 1309.23(b)(1).[48] This regulation is directly applicable to Respondent's use of the storage units.

Notably, at the time this regulation was promulgated, several commenters ''objected to the requirement * * * that a separate registration be obtained for each location at which List I chemical activities are carried out[,]'' and ''suggested that DEA allow companies to obtain a single registration * * * for multiple locations.'' Implementation of the Domestic Chemical Diversion Control Act of 1993, 60 FR 32447, 32448 (1995). As DEA then explained, ''[t]he law is specific on this point. The [Domestic Chemical Diversion Control Act] requires that *a separate registration be obtained at each location at which List I chemicals are distributed*.'' *Id.* (emphasis added).

Relatedly, several commenters asked ''how the requirement for separate registrations for separate locations would apply to [independently owned] warehouses?'' *Id.* DEA explained that ''[t]he person who distributes List I chemicals from independently owned warehouses *must register at each location* and ensure that the other chemical control requirements, including security, record keeping, reporting, etc., for their products are met.'' *Id.* (emphasis added).

The record here clearly establishes that the SLCs which Respondent stores in the self-storage units are not shipped back to Respondent's registered location before being distributed. Rather, the SLCs are distributed directly from the self-storage units to Respondent's customers. As DEA's regulation makes plain, Respondent's self-storage units are therefore subject to the registration requirement. *See* 21 CFR 1309.23(b)(1).

As explained above, Respondent's contention that it was not storing products at the self-storage units is

to sell to it, and sold massive quantities to it in the three months which preceded the suspension.

For similar reasons, I find unpersuasive the testimony of Respondent's Expert that it would be error to draw conclusions from the six stores identified in Government Ex. 38 and 44. *See* Tr. 1697–1705. Indeed, with the exceptions of BPM 55 and NOC 56, it is not even clear that these stores were the largest purchasers.

[45] As noted above, there was a substantial dispute between the parties over the various assumptions necessary to determine what an average convenience store would sell in legitimate commerce. Yet even indulging numerous assumptions favorable to Respondent such as: (1) That only 31,000 stores sell the products, (2) that ephedrine products constitute sixty percent of the SLC market at convenience stores, and (3) that the NACS survey has an error rate of fifty-five percent because some stores erroneously report their sales of ephedrine as general merchandise rather than as cold and cough products, ALJ Ex. 15; and concluding that the average monthly sales figure is $941 a month, more than 100 stores were selling at levels which were statistically significant according to Respondent's expert. *See* Tr. 1700 (noting that being outside of two standard deviations is statistically significant); *id.* at 1704 (use of two standard deviations is ''a very appropriate number'').

I acknowledge that because two standard deviations represents ninety-five percent of a population, by definition 2.5 % of the stores will fall outside of this point on both sides of the curve. In concluding that Respondent does not maintain effective controls against diversion, I do not rely solely on the Z scores calculated by Respondent's expert. *See* RX 27A. I also consider the disparity between the size of the purchases of Respondent's largest customers and its average customer.

[46] The ALJ did note, however, that Respondent ignored the letter of a DEA Group Supervisor which had informed it that its conduct was illegal. ALJ at 91.

[47] Ordinarily, courts defer to agencies when presented with a legal issue that lies within the agency's primary jurisdiction. II Richard J. Pierce, Jr., *Administrative Law Treatise* 917 (4th ed. 2002). The scope of the CSA's registration requirements is such an issue.

[48] The regulation also exempts from registration ''[a]n office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling such sales orders.'' 21 CFR 1309.23(b)(2). This provision is not applicable to Respondent's use of the self-storage units.

absurd. The units are warehouses as that term is understood in common usage. *See Webster's Third New International Dictionary* 2576 (1976) (defining warehouse as ''a structure or room for the storage of merchandise or commodities'').

Respondent nonetheless argues that the drop-off points are not required to be registered because they are not its ''principal place of business.'' Resp. Br. at 97–98. Respondent acknowledges that the term ''principal place of business [is] not defined in the definition section [ ] of the CSA.'' Resp. Br. at 97. Respondent thus contends that the term should be given its ''ordinary meaning.'' *Id.* Relying on several cases interpreting the term ''principal place of business'' for the purpose of determining a corporation's citizenship for the diversity jurisdiction of the federal courts, *see* 28 U.S.C. 1332(c)(1), Respondent contends that ''[t]he principal place of business for a corporation is usually its headquarters, where day-to-day business is conducted.'' *Id.* (citing *Heritage Educ. Trust* v. *Katz,* 287 F.Supp.2d 34 (D.D.C. 2003) and *Masterson-Cook* v. *Criss Bros. Iron Works, Inc.,* 722 F. Supp. 810, 812 (D.D.C. 1989)).

According to Respondent, the Federal courts apply a '' 'nerve center of operation' test to establish the principal place of business of corporations doing business in multiple states[,]'' and that '' [w]hen no one state is clearly the center of corporate activity or accounts for a majority of the company income, the headquarters logically assumes greater importance in determination of the principal place of business.'' *Id.* at 97–98 (quoting *Masterson-Cook,* 722 F. Supp. 812) (other citations omitted). In Respondent's view, its Greenfield, Indiana headquarters ''is clearly the center of corporate activity,'' because ''[a]ll transactions with vendors and customers are handled through the Greenfield offices.'' *Id.* at 98. Relatedly, Respondent argues that ''[t]he drop off units are not the 'center of corporate activity' nor do they 'account for a majority of the company income.' '' *Id.* Respondent's arguments are not persuasive.

It is fundamental that statutory terms take their meaning from the context in which they are used and the statutory purpose. *See Mid-Con Freight Systems, Inc.,* v. *Michigan Pub. Serv. Comm'n,* 545 U.S. 440, 447 (2005); *Tyler* v. *Cain,* 533 U.S. 656, 662 (2001); *see also Pharmaceutical Res. & Mfr's of America* v. *Thompson,* 251 F.3d 219, 224 (D.C. Cir. 2001). Respondent's reliance on cases interpreting the diversity statute ignores the context in which the term ''each principal place of business'' is used in the CSA, as well as the CSA's fundamentally different purpose.

Under Respondent's interpretation, an entity would be required to obtain a registration only for a single location—its headquarters. The text of section 822 demonstrates, however, that Congress did not limit a registrant's obligation to obtain a registration to a single place of business such as its corporate headquarters. Rather, Congress imposed on a registrant the obligation to obtain a separate registration at ''*each* principal place of business * * * where the applicant * * * distributes * * * List I chemicals.'' 21 U.S.C. 822(e) (emphasis added).

Consistent with the underlying purposes of the CSA, the statutory text manifests Congress's understanding that an entity can have multiple principal places of business. A location where List I chemicals are stored and distributed from, is a principal place of business because it plays a ''consequential'' part in the registrant's activity of distributing. *See Webster's Third New Int'l Dictionary* 1802 (1976) (defining ''principal'' in part as ''consequential''). In determining whether a facility is a principal place of business within the meaning of the CSA, the Act looks to the nature of the activity that occurs at the particular location and not at the dollar volume of business that is transacted out of the facility. *See* 21 CFR 1309.23(b)(2) (exempting from registration ''[a]n office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals * * * nor serves as a distribution point for filling sales orders'').

Respondent's interpretation would clearly frustrate the Congressional purpose. In enacting the CSA's registration provisions, Congress' purpose was to protect against diversion by requiring that those persons who propose to engage in the legitimate distribution of controlled substances and listed chemicals apply for a registration, notify this Agency of the proposed location of their activity, and submit the facility for inspection by the Agency to ensure that it has adequate security controls and procedures. *See, e.g.*, 21 U.S.C. 822(f) (authorizing the Attorney General ''to inspect the establishment of a registrant or applicant for registration''). Indeed, inspection by the Agency of a proposed facility is fundamental to the CSA's mandate to protect the public interest. *Id.* 823(h); *see also* 21 CFR 1309.41.

As the record here establishes, Respondent has never applied for registration for any of its storage units and has never submitted any of its storage units for inspection. Indeed, according to the record, Respondent has yet to provide information regarding the location of some 34 of its storage units. As this case demonstrates, adopting Respondent's interpretation would frustrate Congress's purpose and render the Act a nullity.

Respondent's interpretation would also create a perverse incentive. While it is unclear whether under its view an entity which has only a few warehouses would have to obtain a registration for each of them, *see* Resp. Br. at 97–98,[49] what is clear is that an interpretation which determines whether a facility must be registered by looking to the amount of business activity that occurs out of a facility rather than the nature of the activity that occurs therein, would encourage an entity to keep adding warehouses or storage facilities so that it could eventually claim that its warehouses were no longer principal places of business and were thus not subject to the registration requirement. Adopting Respondent's interpretation would thus lead to absurd results and seriously undermine the security of the Nation's controlled substances and listed chemical supplies. I therefore reject it.

As stated above, the ALJ did not address this statutory question. She did, however, conclude that Respondent's conduct in continuing to store SLCs at, and distributing them from, the self-storage units, even after receiving the Group Supervisor's letter, was ''not consistent with the requirements for a participant in a regulated industry,'' and supported the revocation of its registration. ALJ at 91. Respondent excepts to the ALJ's conclusion, contending that it was placed in the ''dilemma'' that if it complied with the letter, it would have to use common carriers and that this ''would increase the risk of diversion.'' Resp. Exceptions at 99. Respondent further argues that because it ''questioned the legal validity of the letter, and feared adherence to it would cause [it] to contribute to the risk of diversion to the illicit methamphetamine trade, it filed suit'' in federal court. *Id.* at 100.

Respondent's argument is patently self-serving and unsupported by the record. As found above, Respondent's evidence as to the perceived security inadequacies of, and increased risk of

[49] Respondent's argument that ''the principal place of business for a corporation is usually its headquarters,'' Resp. Br. 98, suggests that its view is that only one registration is required for an entity no matter the geographic scope of its distribution activities.

diversion when shipping via common carriers, lacked foundation. It presented no evidence of any diversion of SLCs when being shipped by common carriers.[50] The argument further ignores the significant risk of diversion posed by its own distribution model, both through its use of the storage units which do not provide an acceptable level of security, and its further practice under which SLCs may be stored on a salesperson's truck for up to nine days at a time.

Finally, Respondent contends that because it was not sure what the legal effect of the letter was, it felt obliged to challenge the letter by filing suit. Contrary to Respondent's view, its right to seek declaratory relief in federal court is not at issue. *Cf. id.* at 100. (arguing that ALJ's decision ''[c]ondemns the exercise of'' its right to seek relief in a federal court). Rather, what is at issue is Respondent's decision to continue to distribute SLCs—for some forty-four months—in a manner that violates Federal law, and its doing so even after being told that it was violating Federal law.

Furthermore, even if there was a legitimate question as to the legal effect of the letter, the Agency's regulation made clear that a warehouse was not exempt from registration if the SLCs being stored therein ''are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered.'' 21 CFR 1309.23(a)(1). I thus conclude that the Agency's regulation and the letter provided Respondent with ample notice that its conduct was illegal.[51] Notwithstanding Respondent's assertion that it is now willing to comply with Federal law, its deliberate disregard of the warning it received and lengthy failure to comply, strongly support the revocation of its registration.[52]

Factor Four—Past Experience in the Distribution of Chemicals

In discussing this factor, the ALJ noted that Respondent has been registered since 1998 and thus had extensive experience in distributing SLCs. ALJ at 92–93. She further explained that prior to the service of the Suspension Order, ''Respondent had not been informed by the [agency] of any incidents of diversion of its SLC product,'' and that with the exception of the 2004 letter regarding its distribution practices, it was ''never informed * * * of any statutory or regulatory violations.'' *Id.* at 93. Finally, the ALJ noted that the Agency had renewed ''Respondent's registration annually between 1998 and 2007.'' *Id.* Based on what she characterized as Respondent's ''nine year history of compliance,'' the ALJ concluded that the evidence on this factor ''support[ed] a remedy less severe than revocation.'' *Id.*

The ALJ's conclusion is mistaken for several reasons. First, the ALJ's conclusion that Respondent had not been informed by the Agency of any incident of diversion is contrary to the evidence, which establishes that twenty-two sixty-count bottles of products it distributed were found at an illicit laboratory in Connecticut and that a DI discussed the matter with its executives. Tr. 1082–84. Whether the subject was first broached by the DI or Respondent is beside the point, as is whether the information was put in a formal warning letter. The fact remains that products which it distributed were diverted. Moreover, while Respondent provided the investigator with information as to which of its salespersons had received the products, it could not identify the stores to which the products were distributed. Tr. 1517.

Second, the ALJ gave insufficient weight to Respondent's continuation of its illegal practice of distributing out of unregistered storage units for more than three and a half years after having been advised of the practice's illegality. Most significantly, at no point did Respondent voluntarily cease the practice.

Moreover, as explained above under factor two, the registration requirement is one of the essential features of the CSA. Respondent's violations are not technical violations of the Act. Respondent's conduct thus precludes a finding that Respondent's experience establishes a ''history of compliance.'' ALJ at 93. Respondent's experience thus also supports the conclusion that its registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h).[53]

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

As found above, following the service of the Immediate Suspension, Respondent contacted one of its suppliers and attempted to enter into a scheme under which its sales force would continue to take orders for SLCs, which would be sent to its headquarters and then on to the supplier, which would ship the products. Under the scheme, Respondent's salespersons would ''still do all reordering and stocking of the merchandise as [they] have in the past.'' GX 48.

At the hearing, one of Respondent's vice presidents attempted to justify the scheme, explaining that under his ''definition of sales, we're not involved in the distribution of the product. But our sales people are in that store functioning as an agent.'' Tr. 2402. While the supplier refused to enter into the scheme, the VP testified that it was ''[s]omething that were still continuing to explore.'' *Id.* at 2403.

In its Exceptions, Respondent contends that ''[u]nder 21 CFR 1309.23, sales agents are not required to be registered and are lawful.'' Resp. Exceptions at 102. Respondent further argues that because it ''only discerned select customer's interest in it serving in this role,'' *id.* at 103, the ALJ's conclusion that it ''still does not seem to understand that it is working in a highly regulated industry when it actually handles SLC products,'' ALJ at 92, condemns it based on ''the mere expression of interest in a legal option.'' Resp. Exceptions at 103.

Respondent is correct that because it never actually entered the scheme, there is no basis for concluding that its actions related to the scheme demonstrate that it failed to comply with applicable laws. *See* 21 U.S.C. 823(h)(2). The scope of factor five is, however, considerably broader than factor two, and encompasses ''such other factors as are relevant to and consistent with the public health and safety.'' *Id.* 823(h)(5).

Respondent's assertion that it merely expressed interest in a legal option mischaracterizes the record. Respondent's actions were not limited

[50] Respondent also argues that ''the Raber letter would allow reliance on a system of distribution (FedEx and UPS unregistered locations) that present risks of diversion that exceed those of [its] system.'' Resp. Exceptions at 101. Congress however, has specifically exempted common carriers from registration, *see* 21 U.S.C. 822(c)(2), and has concluded that their use for shipping controlled substances and listed chemicals poses an acceptable risk of diversion. I further note that Respondent acknowledged in testimony that it has used common carriers in the past.

[51] Nor did Respondent seek review of the Group Supervisor's letter within the Agency.

[52] As noted under factor one, Respondent also failed to comply with Federal law because it did not maintain proper records of regulated transactions.

[53] The ALJ's further reliance on the Agency's renewal of Respondent's registration was in error. Under Federal Regulations, in the event the Agency proposes the denial of a renewal application, it must issue an Order to Show Cause. 21 CFR 1309.42(a). There are a variety of reasons why the Agency may not be prepared to go forward with a Show Cause Proceeding at a particular time including, *inter alia,* a lack of resources, the complexity of the matters under investigation, and the need to pursue other enforcement priorities. Moreover, field personnel may approve the renewal of a registration based on an erroneous understanding of the law and regulations. The decision to renew a registration is thus not probative of a registrant's record of compliance with Federal law and Agency regulations.

to merely thinking about a legal option or seeking legal advice about the scheme. Rather, it affirmatively sought out one of its suppliers and attempted to induce it to enter the scheme only to be rebuffed by the supplier.

While Respondent maintains that it was pursuing a legal option because an agent is not required to be registered, it ignores that this exception applies only if the ''agent * * * is acting in the usual course of [its] business.'' 21 U.S.C. 822(c)(1); 21 CFR 1309.24(a). The usual course of Respondent's business with respect to SLCs did not, however, involve acting as a sales agent for another registrant. Rather, the usual course of its business was distributing SLCs for its own account. More significantly, I further hold that an entity does not act in the usual course of business when it engages in distribution-related activities that it has previously been prohibited from doing pursuant to an order suspending or revoking its registration. It would fundamentally undermine the CSA's purpose of protecting against diversion to allow an entity whose registration has been suspended or revoked to subsequently engage in the same or related activities as an agent.

Respondent's attempt to circumvent the suspension order—and the admission of one its executives at the hearing that it was still exploring this option—reflects adversely on its fitness to engage in the distribution of SLCs. I thus conclude that this factor also supports the conclusion that Respondent's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h)(5).[54]

Sanction

Under DEA precedent, the Agency considers all of the facts and circumstances in determining the appropriate sanction. *See Martha Hernandez, M.D.*, 62 FR 61,145 (1997). While the ALJ found that factors one and two supported revocation, and that ''Respondent's actions appeared to blatantly disobey a DEA directive,'' she further reasoned that except for this letter, ''Respondent has not been given an opportunity to remedy the flaws identified * * * in this action.'' ALJ at 100. Based on what she characterized as its ''history of compliance, as evidenced by'' the Agency's continuing its registration, as well as ''its financial commitment to compliance, as evidenced by its rework of its hand-held computer system to better track inventory,'' the ALJ reasoned that revocation ''does not seem consistent with prior agency action concerning this Respondent.'' ALJ at 100–101. Based on this view of the record, the ALJ further opined ''that this is a case where teamwork between the DEA and this major distributor would facilitate the public interest.'' *Id.* at 101. The ALJ thus recommended that I continue Respondent's registration while imposing compliance conditions.

Were the evidence limited to Respondent's recordkeeping problems, imposing compliance conditions might well protect the public interest. But it is not. I acknowledge that the evidence points to some measures which Respondent voluntarily undertook such as reprogramming its computer system,[55] providing its customers with materials on the CMEA and its self-certification requirement, logbooks, and plexiglass cabinets. Its customers could not, however, legally sell its products without self-certifying and maintaining logbooks. Moreover, these measures do not address the serious problems with its distribution practices that are established by the record, and which were either ignored, or discounted by the ALJ.

First, for more than three and a half years, Respondent disregarded a DEA letter specifically warning it that its use of the 150–180 self-storage units to store and distribute SLCs violated Federal law. Moreover, Respondent continued to violate Federal law up until its registration was suspended. As explained above, these are not technical violations, but rather transgressions of one of the CSA's fundamental provisions. Respondent's disregard of the letter and continuation of its practices for some forty-four months makes its conduct especially egregious. Given the sustained nature of the violations and Respondent's failure to voluntarily cease its misconduct, its assertion that it is now willing to ''modify[] its existing system of distribution,'' Resp. Exc. 90, is not persuasive. *Cf. ALRA Laboratories, Inc.*, v. *DEA*, 54 F.3d 450, 452 (7th Cir. 1995) (''[a]n agency rationally may conclude that past performance is the best predictor of future performance''); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36503 (2007) (rejecting company's claims of reform in light of the scope and duration of its misconduct and failure to heed information that its activities were contributing to diversion).

Second, while Respondent asserted that it imposed sales limits on how much of each product a store could buy in a service cycle, and that it monitored the purchases of each product at each store throughout the week to determine whether a store was purchasing excessive quantities, investigated if it was, and cutoff sales to those store which were purchasing excessive amounts, it is clear that these policies were frequently ignored. Putting aside the effectiveness of the one case per product, per service cycle policy,[56] the credited testimony establishes that its sales force violated the policy some 85 times in the six months preceding the July 2007 inspection. Moreover, Respondent only started issuing warning letters to its sales force in August 2007—a month after the warrant was executed—with one of its executives offering the lame excuse that he had not received the reports until then because of a computer ''glitch.''

Notably, Respondent's CEO testified that if a customer obtained more than a case of a product in a service cycle, he ''would cut them off, [and] stop the sale of product to them.'' Tr.159. Respondent, however, produced no evidence that it had ever entirely cut off a customer.

Indeed, Respondent's own evidence with respect to store BPM55—a store at which five persons purchased quantities that are grossly inconsistent with use of the products to treat asthma and are consistent with diversion—amply demonstrates the disingenuousness of its claim that it monitors its customers' purchases and cuts off sales if a store is acquiring excessive amounts. Notwithstanding that it had previously developed concerns regarding this store's excessive purchases, in the three months prior to the suspension order, Respondent sold to it products with a monthly average retail value of more than $7300, an amount more than eleven times its average customer's purchase.[57] Respondent's sales to this store amply demonstrate that its policy of monitoring ''unusual sales activity'' and cutting off sales if such purchases

[54] As explained above at n. 5, the issue of whether there is a legitimate medical need for over-the-counter ephedrine products, *see* ALJ at 94–95, is for the FDA to decide. The issue in this proceeding is whether Respondent's registration is consistent with the public interest.

[55] It is, however, unclear whether the reprogramming has rectified the problems identified with the salespersons' entry of product codes.

[56] As explained above, the policy's limit was imposed on a per-product and per-service cycle basis. Most stores were serviced every two weeks and some were serviced weekly. Moreover, Respondent sold ten different products. Accordingly, a store being serviced weekly could buy up to forty cases every four weeks.

[57] As found above, the record also shows numerous other stores to which Respondent repeatedly sold quantities that exceeded its average customer's purchases by a wide margin.

continue, RX 10, at 1, is a sham and not a legitimate effort to control diversion.

Respondent's failure to enforce its own policies provides reason alone to conclude that it cannot be trusted to adhere to compliance conditions. This conclusion is further supported by Respondent's sustained and flagrant violations of Federal law, as well as its attempt to circumvent the suspension order. Indeed, as Respondent's history amply demonstrates, its professed commitment to ''teamwork'' and ''to become a compliance model for the entire industry,'' Resp. Ex. at 139, cannot be taken seriously.[58] I therefore conclude that imposing compliance conditions would not adequately protect the public interest, and reject the ALJ's recommendation.[59]

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, 003563NSY, issued to Novelty Distributors, D/B/A/ Greenfield Labs, be, and it hereby is, revoked. I further order that any pending application of Novelty Distributors, D/B/A Greenfield Labs, for renewal of its registration, be, and it hereby is, denied. This order is effective immediately.

Dated: September 3, 2008.

Michele M. Leonhart,

Deputy Administrator.

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BILLING CODE 4410–09–P

[58] For the same reasons, I find unpersuasive the August 13, 2008 letter from Respondent's President.

[59] Respondent raises a plethora of claims that the Agency or its personnel have violated its rights under the First and Fifth Amendments, as well as statutory provisions including the Administrative Procedure Act, the Data Quality Act, and 21 U.S.C. 880. *See* Resp. Br. at 114–39. For example, Respondent asserts that the DIs violated its First Amendment rights and engaged in a prior restraint because they refused to allow its executives to videotape them as they reviewed Respondent's records. *See id.* at 116. It also alleges that a DI committed an assault and battery during the inspection when he grabbed a video recorder from the hands of one of its executives who was attempting to set up the camera in order to tape the investigators while they reviewed Respondent's records.

While in my order denying Respondent's interlocutory appeal, I adhered to settled Agency precedent that the exclusionary rule does not apply in these proceedings, ALJ Ex. 13, at 3; Respondent now contends that I should discount the testimony of two DIs who participated in the inspection to deter future violations. Indeed, Respondent even contends that I should discount the testimony of these DIs based on the alleged assault and battery of the third DI, who did not testify at the hearing.

Having considered the legal and factual bases for each of Respondent's claims, I conclude that none of them presents a substantial question as to the fundamental fairness of this proceeding and none warrants further discussion.

DEPARTMENT OF LABOR

Office of the Secretary; Submission for OMB Review: Comment Request

September 5, 2008.

The Department of Labor (DOL) hereby announces the submission of the following public information collection requests (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 each 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 Darrin King on 202–693–4129 (this is not a toll-free number)/e-mail: *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 Occupational Safety and Health Administration (OSHA), 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: Occupational Safety and Health Administration.

Type of Review: Extension without change of a previously approved collection.

Title of Collection: Slings (29 CFR 1910.184).

OMB Control Number: 1218–0223.

Affected Public: Private Sector.

Estimated Number of Respondents: 1,000,000.

Estimated Total Annual Burden Hours: 17,760.

Estimated Total Annual Costs Burden: $0.

Description: The provisions of the standard require that the employer make a periodic inspection of alloy steel chain slings at least once a year and to make and maintain a record of the inspection. It also requires the employer to ensure that each new, repaired or reconditioned alloy steel chain sling is proof tested and a certification record maintained. In addition, the standard requires the employer to maintain a record of the proof test on wire rope slings. For additional information, see related 60-day preclearance notice published at 73 FR 35412 on June 23, 2008. PRA documentation prepared in association with the preclearance notice is available on *http://www.regulations.gov* under docket number OSHA 2008–0020.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension without change of a previously approved collection.

Title of Collection: Forging Machines (29 CFR 1910.218).

OMB Control Number: 1218–0228.

Affected Public: Private Sector.

Estimated Number of Respondents: 27,700.

Estimated Total Annual Burden Hours: 187,264.

Estimated Total Annual Costs Burden: $0.

Description: The Standard requires employers to establish periodic inspections of forging machines, guards, and point-of-operation protection devices and to mark manually controlled valves and switches. These requirements reduce employees' risk of death or serious injury by ensuring that forging machines used by them are in safe operating condition, and that they are able to identify manually operated valves and switches. For additional information, see related 60-day preclearance notice published at 73 FR 35414 on June 23, 2008. PRA documentation prepared in association with the preclearance notice is available