portion of Respondent's products were diverted. Accordingly, I therefore conclude that Respondent's continued registration ''is inconsistent with the public interest.'' *Id.* § 823(h).

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, 003001ATY, issued to Archer's Trading Company be, and it hereby is, revoked. I further order that Archer Trading Company's pending applications for modification and renewal of its registration be, and they hereby are, denied. This order is effective August 31, 2007.

Dated: July 20, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–33]

Holloway Distributing; Revocation of Registration

On May 25, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Holloway Distributing, Inc. (Respondent), of Puxico, Missouri. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, 003219HIY, and the denial of Respondent's pending application for renewal of its registration, on the ground that its continued registration ''is inconsistent with the public interest.'' Show Cause Order at 1.

More specifically, the Show Cause Order alleged that Respondent distributed list I chemical products containing pseudoephedrine, a precursor chemical used in the illicit manufacture of methamphetamine, a schedule II controlled substance, to convenience stores, gas stations, liquor and video stores, and bait and tackle shops in various parts of Missouri, the State which has repeatedly ranked first in the nation in the number of clandestine methamphetamine lab seizures. *Id.* at 2. The Show Cause Order alleged that these establishments constitute the non-traditional market for consumers who purchase pseudoephedrine products for legitimate uses. *Id.* at 7. The Show Cause Order further alleged that Respondent's ''sale of pseudoephedrine products is inconsistent with the known legitimate market and known end-user demand for products of this type.'' *Id.*

The Show Cause Order also alleged that in March 2004, DEA investigators conducted verifications of several entities which Respondent identified as its customers. *Id.* at 3–4. According to the allegations, DEA investigators determined that several of Respondent's customers were purchasing additional list I chemical products from other distributors and also selling other products such as starting fluid and lantern fuel which are used in the illicit manufacture of methamphetamine. *Id.*

The Show Cause Order next alleged that in March 2004, as part of a regulatory investigation of Respondent, DEA investigators conducted an accountability audit of five list I chemical products. *Id.* at 5. The Show Cause Order alleged that there were either overages or shortages for each product, and that DEA investigators found that Respondent had ''failed to notify the agency of a significant loss of List I chemical products as required by 21 U.S.C. 830(b)(1)(C) and 21 CFR 1310.05(a)(3).'' *Id.*

Finally, the Show Cause Order alleged that between November 7, 2003, and April 1, 2004, Respondent sold pseudoephedrine products on numerous occasions to one Keith Frankum, notwithstanding that Frankum had presented a sales tax exempt certificate which indicated that his business address was a local storage facility and was vague when asked about the nature of his business. *Id.* at 5–6. According to the allegations, notwithstanding that local law enforcement authorities had told one of Respondent's employees that Frankum's brother was ''a meth cook,'' and that its employees ''referred to [Frankum] as 'the drug guy' whenever he arrived at Holloway to make a purchase,'' Respondent made additional sales of pseudoephedrine products to him. *Id.* at 6. The Show Cause Order further alleged that in early April 2004, Frankum was arrested and during a search incident to the arrest, was found to be in possession of twenty boxes of pseudoephedrine products sold by Respondent, an invoice from Respondent, and a handwritten note which read: ''Be careful when leaving here!'' *Id.* at 5. According to the allegations, Frankum subsequently told DEA investigators that he sold pseudoephedrine ''to several repeat customers'' and that it ''was a big seller because it was used to make drugs.'' *Id.* at 6. The Show Cause Order also alleged that Frankum admitted that he had a prior arrest for possession of methamphetamine and that he had done ''a lot of meth'' five years earlier. *Id.* The Show Cause Order further alleged that Respondent never reported to DEA its sales to Frankum. *Id.* at 5.

On June 24, 2005, Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Gail A. Randall, who conducted a hearing in Arlington, Virginia, on February 7, 2006, and in Cape Girardeau, Missouri, on February 22–23, 2006. During the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted briefs containing proposed findings of fact, conclusions of law and argument.

On December 19, 2006, the ALJ submitted her recommended decision (hereinafter, ALJ). In her decision, the ALJ concluded that the Government had ''initially * * * met its burden of proof * * * by demonstrating that the Respondent made 'grossly excessive sales' of listed chemical products between October 1, 2003, and March 23, 2004.'' ALJ at 40 (citing FOF 26). The ALJ also acknowledged DEA precedent holding that a registrant's grossly excessive sales support a finding that its products were diverted and that its continued registration would be inconsistent with the public interest. *Id.* at 40–41.

The ALJ concluded, however, that Respondent's continued registration would not be inconsistent with the public interest for two reasons. *Id.* at 41. First, the ALJ noted that Respondent had ''demonstrated its willingness and its ability to develop and implement changes in its business processes consistent with the [agency's] recommendations.'' *Id.* Second, the ALJ relied on Missouri's recently enacted restrictions on pseudoephedrine sales. According to the ALJ, the statute showed that ''the State will be monitoring the gelcap and liquid pseudoephedrine products, if any, found in the methamphetamine labs,'' and that ''[s]uch heightened scrutiny leads to the conclusion that, if the products of the Respondent, as well as other distributors of List I chemical products in Missouri, are found in illicit methamphetamine laboratories, the State will close the legislative loophole afforded these limited products.'' *Id.* The ALJ reasoned that ''[u]ntil such time as the problem is substantiated * * * the possibility of * * * Respondent's products being diverted [should] not be relied upon to revoke'' its registration. *Id.* The ALJ therefore recommended that I not revoke

Respondent's registration and not deny its pending application for renewal.

On January 5, 2007, the Government filed exceptions to the ALJ's decision. On February 1, 2007, the ALJ forwarded the record to me for final agency action. Having reviewed the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's findings of fact except as noted herein. I reject, however, the ALJ's conclusions of law with respect to factors one, two, four and five. I further reject the ALJ's ultimate conclusion that Respondent's continued registration ''would not be inconsistent with the public interest.'' *Id.* Accordingly, I also reject the ALJ's recommendation that Respondent's registration should not be revoked and its pending renewal application should not be denied. I make the following findings.

Findings of Fact

Respondent is a Missouri Corporation which is located at 210 East Owen Avenue, Puxico, Missouri. ALJ Ex. 2. Respondent is co-owned by Mr. Terry Holloway and his wife, Debbie Holloway. Tr. 720. Mr. Holloway is Respondent's president. *Id.* Respondent is a wholesale distributor of approximately 10,000 products including groceries, restaurant foods, candy, cigarettes, and tobacco. *Id.* at 724.

Respondent, which has been registered since 1998, currently holds DEA Certificate of Registration, 003219HIY, which authorizes it to distribute list I chemicals. Gov. Ex. 1 & 2. Based on Respondent's submission of a timely renewal application in September 2004, Respondent's registration has remained in effect pending the final order in this matter. Gov. Ex. 2.

Methamphetamine and the Market for List I Chemicals

Pseudoephedrine is lawfully marketed under the Food, Drug and Cosmetic Act as a decongestant. Gov. Ex. 4, at 4. Pseudoephedrine is, however, also regulated as a list I chemical under the Controlled Substances Act (CSA) because it is easily extracted from non-prescription drug products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. *See* 21 U.S.C. 802(34); 21 CFR 1308.12(d).

Methamphetamine ''is a powerful and addictive central nervous system stimulant.'' *T. Young Associates, Inc.*, 71 FR 60567 (2006) (other citations omitted). As noted in numerous DEA final orders, the illegal manufacture and abuse of methamphetamine pose a grave threat to this country. *See id.* Methamphetamine abuse has destroyed numerous lives and families. *Id.* Moreover, because of the toxic nature of the chemicals used in making the drug, illicit methamphetamine laboratories cause serious environmental harms. *Id.*

The illicit manufacture and abuse of methamphetamine is an extraordinarily serious problem in Missouri. According to the record, during the years 2001 through 2004, Missouri repeatedly ranked first in the number of law enforcement seizures of methamphetamine laboratories. *See* Gov. Ex. 3, at 4. More specifically, in 2001, law enforcement authorities seized 2,181 labs; in 2003, 2,885 labs; and in 2004, 2,782 labs. *Id.* Moreover, while legislation enacted by Missouri in June 2005 (which made pseudoephedrine and ephedrine in tablet-form a schedule V controlled substance and limited its sale to pharmacies), appears to have led to a substantial reduction in the number of meth. lab seizures, law enforcement authorities still seized 745 labs in the latter half of 2005. *See* Gov. Ex. 28.

The Missouri statute, however, exempts pseudoephedrine in liquid and liquid-filled gel caps. *See* Mo. Rev. Stat. 195.017.17; Tr. 309–11. Thus, in Missouri, these products can be sold by non-pharmacies. According to the record, ''[w]hile the vast majority of clandestine laboratories seized have utilized tableted pseudoephedrine and ephedrine products, gel-caps and liquid dosage form products can easily serve as a source of precursor material for the production of methamphetamine.'' Gov. Ex. 4, at 8. Furthermore, DEA studies show that pseudoephedrine ''can be easily extracted'' from liquid and gel cap products by using reagents and solvents which are ''readily available at hardware and auto parts stores in the U.S.'' *Id.; see also* Gov. Ex. 6 (discussing study by DEA chemist who was able to extract pseudoephedrine from gel caps and obtain a 68 percent yield using equipment typically found in meth. labs). The record further establishes that in those States (including Missouri) which have exempted gel cap and liquid form listed chemical products, traffickers are using exempted products to make meth. *See* Gov. Ex. 5, at 13–14; Gov. Ex. 6, Gov. Ex. 7, Tr. 321–22.

The Government also established that there is both a traditional and non-traditional market for pseudoephedrine. According to Jonathan Robbin, who has testified as an expert in statistical analysis of demographic, economic, geographic, survey and sales data in numerous DEA proceedings and several criminal and civil trials, over 97 percent of all non-prescription drug products are sold by drug stores, pharmacies, supermarkets, large discount merchandisers, and electronic shopping and mail order houses. Tr. 173. Mr. Robbin further testified that sales of non-prescription drugs by convenience stores (including both those that sell and do not sell gasoline), ''account for only 2.2% of the overall sales of all convenience stores that handle the line and only 0.7% of the total sales of all convenience stores.'' Gov. Ex. 8, at 5. Based on his study of U.S. Government Economic Census data, survey data obtained by the National Association of Convenience Stores, and commercially available point-of-transaction data, Mr. Robbin further stated that only about 1.2 percent of all non-prescription drug products are sold at convenience stores, Tr. 173, and cold remedies (including pseudoephedrine products) ''are [a] * * * much smaller'' portion of this. *Id.* at 174; Gov. Ex. 8, at 5. Mr. Robbin thus explained that convenience stores ''definitely constitute a 'nontraditional market' for the sale of [OTC] non-prescription drug pseudoephedrine'' products. Gov. Ex. 8, at 5.

Mr. Robbin further testified that ''the normal expected retail sale of pseudoephedrine (Hcl) tablets in a convenience store may range between $0 and $40 per month[,] with an average of $19.85 per month,'' and that the expected sales range of Actifed tablets in a convenience store ranges between $0 and $20 [per month], with an average of $ 8.68.'' *Id.* at 8; Tr. 176. Mr. Robbin explained that ''[a] monthly retail sale of $60 of pseudoephedrine (Hcl) * * * would be expected to occur less than one in 1,000 times in random sampling,'' and [a] monthly retail sale of $100 a month of pseudoephedrine (Hcl) or of $50 of Actifed tablets would be expected to occur about once in a million times in random sampling.'' Mr. Robbin also stated that gas stations without convenience stores, liquor stores, sporting goods stores, bait shops, video stores, gift stores, and head shops sell only ''trace amounts'' of these products. Gov. Ex. 8, at 8.

DEA investigators provided Mr. Robbin with a list of 1,371 transactions in which Respondent distributed either Select Brand [s]udafed or [a]ctifed during the period from October 1, 2003, through March 23, 2004. *Id.* at 12. The products were sold to 94 stores which included convenience stores, gas stations and liquor stores. *Id.* According to the data, Respondent distributed 3,129 packages of Select Brand [s]udafed, each containing 24 tablets, and 5,858 packages of Select Brand

[a]ctifed, each also containing 24 tablets. Gov. Ex. 8, at 12–13.

Based on information obtained from Thomson Micromedex's Red Book, Mr. Robbin initially calculated an implied retail sales value of $4.58 for Respondent's sudafed product and $4.34 for the actifed product. *Id.* at 12. Based on these values, Mr. Robbin then tabulated the imputed monthly sales of these products by Respondent's customers and calculated the probability that the sales were to meet legitimate consumer demand for the products. *See* Gov. Ex. 9, at B1–B10. Mr. Robbin found that ten of the seventy-five stores selling the sudafed had sold ten times the expected amount, and another five stores sold five to ten times expectation. Gov. Ex. 8, at 14. With respect to the actifed product, ''49 of the 71 stores (69.01%)'' sold amounts which Mr. Robbin described as ''extraordinarily excessive when compared to normal expectations.'' *Id.* at 15.

Respondent did not, however, sell name brand Sudafed and Actifed, but rather, a generic brand. The evidence established that the suggested retail price (SRP) of these products was $1.83 for the generic sudafed and $2.81 for the generic actifed although Respondent did not produce any evidence establishing that its customers actually sold the product at the SRP.[1] *See* Gov. Ex. 16, at 7, Gov. Ex. 23, at 2.

The Government therefore entered as a rebuttal exhibit a new tabulation of the average monthly sales by Respondent's customers. *See* Gov. Ex. 29. According to this table, three stores were selling the sudafed products at ten times expectation; another eight stores were selling the product at five to seven times expectation. *Id.* at B7.

The data for the stores selling actifed was even more pronounced. This tabulation showed that one store was selling at over fifty times expectation, seven stores were selling at twenty-five to fifty times expectation, eleven stores were selling at ten to twenty-five times expectation, and another eleven stores were selling at five to ten times expectation. *Id.* at B10–B12.

In his testimony, Mr. Robbin acknowledged that reducing the estimated retail price by half would ''certainly put more stores into the insignificant range.'' Tr. 279. Mr. Robbin, however, further testified that it would ''still leave a great many stores in the significant range.'' *Id.* Mr. Robbin also stated that even if he reduced the estimated retail ''price in half,'' he would still conclude that Respondent's sales were ''excessive.'' *Id.* at 254.

Mr. Robbin further testified that he ''rule[d] out [the] location [of Respondent's customers] as being a factor in the degree of sales.'' *Id.* at 183. According to Mr. Robbin, wherever [people] live in Missouri,'' there is a ''a major pharmacy [or] chain pharmacy'' within ''a half an hour drive time.'' *Id.* at 181. While acknowledging that a convenience store might be a five to ten minute drive, Mr. Robbin reiterated that ''ninety-seven percent'' of shoppers ''buy their non-prescription drugs in pharmacies and supermarkets.'' *Id.* According to Mr. Robbin's testimony, ''non-prescription drugs are bad sellers in convenience stores. They are given very little shelf space, and * * * are classed among the impulse goods, meaning that nobody goes to a convenience store, or few people do, to buy them specifically.'' *Id.* at 182. Mr. Robbin thus ''rule[d] out location as being a factor in the degree of sales,'' because while location might influence sales fifty percent either way (depending upon whether the store was in a rural or urban area), the differences between the expected sales range and Respondent's actual sales were ''vastly greater than fifty percent.'' *Id.* at 183–84.

The ALJ found credible the testimony of Mr. Terry Holloway (Respondent's President and co-owner) that Doniphan, Missouri, a town in Respondent's market, is forty miles from a store in the traditional market. ALJ at 9–10. Mr. Holloway also testified that Doniphan was a town of 3,000 people and had ''a lot of attractions'' such as a river, which apparently is popular with canoeists, and campgrounds. Tr. 727. Mr. Robbin's conclusion that Respondent's customers had engaged in excessive sales was based, however, on sales that occurred in the October to March time frame, a period in which it does not seem likely that tourists would be flocking to Doniphan to go camping or canoeing. But in any event, Mr. Holloway's testimony does no more than call into question Mr. Robbin's conclusion regarding a few stores.[2] Neither it nor the ALJ's observation that ''in some instances * * * Respondent sold list I chemical products in quantities much lower than expected,'' ALJ at 12 (FOF 27), refutes Mr. Robbin's ultimate finding that Respondent ''provides services to retailers outside the traditional market for [OTC] drug products and frequently has sold products containing pseudoephedrine (hcl) in extraordinary excess of normal or traditional demand.'' Gov. Ex. 8, at 17–18.

The DEA Investigation of Respondent

In September 2003, a Diversion Investigator (DI) in the St. Louis Field Division was advised by a DEA Special Agent with the Cape Girardeau field office that Southeastern Missouri Drug Task Force officers were concerned that pseudoephedrine products being found in clandestine meth. labs had come from Respondent's customers. Tr. 348, 354–55. In particular, the Special Agent told the DI that ''some of [Respondent's] customers were selling case quantities * * * out the back door'' of their stores. *Id.* at 355. The DI advised his Group Supervisor of the report and Respondent was scheduled for a regulatory investigation. *Id.* at 348–49.

On March 23, 2004, the DI visited Respondent's registered location and conducted an inspection. Gov. Ex. 13. As part of the inspection, the DI conducted an accountability audit of five highly diverted list I chemical products including three products which contain 30 mg. of pseudoephedrine hydrochloride per tablet (Select Brand sudafed, Select Brand Sinus Allergy, and Contac Sever Cold & Flu Max Strength) and two products which contain 60 mg. of pseudoephedrine tablet (Select Brand Antihistamine Nasal Decongestant (actifed) and BC Allergy Sinus Headache). Gov. Ex. 21; Tr. 389. Accordingly, in the presence of one Respondent's employees, the DI inventoried these products. Gov. Ex. 21.

The DI then proceeded to audit Respondent's handling of the products during the period beginning on October 1, 2003, through the close of business on March 23, 2004, and recorded the results on a chart.[3] Gov. Ex. 22. Initially, the DI concluded that one of the products, Select Brand pseudoephedrine had an overage. *Id.* at 1. The DI also determined that Respondent had shortages in each of the remaining products. *Id.* Most significantly, Respondent was short 105 boxes of Select Brand Antihistamine Nasal Decongestant. *Id.* Respondent was also short five boxes of Select Brand Sinus Allergy, two boxes of Contac

[1] Indeed, there is evidence that some of Respondent's customers sold it for even higher prices than that used by Mr. Robbin. See Tr. 412.

[2] Mr. Holloway also testified that Fisk, Missouri, another town in Respondent's market, was located fifteen miles from a store in a traditional market. Tr. 729. Beyond the fact that fifteen miles on rural roads does not seem to be an excessively long drive, Mr. Robbin's analysis lists only one store as being located in Fisk. *See Generally* Gov. Ex. 29. Respondent's evidence thus does not provide reason to question Mr. Robbin's conclusion that numerous other stores had engaged in excessive sales of pseudoephedrine products.

[3] The DI established the beginning count based on Respondent's computer records. Tr. 392.

Severe Cold and Flu, and one box of BC Allergy Sinus. *Id.*

The first chart did not, however, include Respondent's manual adjustments to inventory because Respondent had not properly documented them. Tr. 394–95. Nonetheless, the DI gave Respondent the ''benefit of the doubt that [the] manual adjustments * * * were * * * correct'' and prepared a second chart. *Id.* Respondent gave two explanations for the adjustments: (1) That the sudafed and actifed products were stored next to each other on the shelf and that an employee could have recorded one product when he had actually pulled the other product for distribution, and (2) that some products were bound together so that six boxes of a product might have been recorded as one box. *Id.* at 396.

According to the second computation chart, Respondent still had shortages of each product. The most significant shortage (Select Brand [a]ctifed) had been reduced from 105 boxes to one. Gov. Ex. 22, at 2; Tr. 397–98. Another product, Select Brand [p]seudoephedrine, had gone from an overage of thirteen boxes to a shortage of thirteen boxes.[4] Gov. Ex. 22, at 2.

Following the initial on-site inspection, the DI visited seven of Respondent's customers including several convenience stores, a liquor store, a video store, and a gas station. Tr. 403–04; Gov. Ex. 25. The first store the DI visited was Millie's, a Citgo gas station located in Wappapello, Missouri. There, the DI found that the store was selling not only listed chemicals products it obtained from Respondent, but also Pro Active ephedrine products that were carried by another supplier. Tr. 405–06.

The DI next visited Green's Grocery in Doniphan, Missouri. *Id.* at 406. There, the DI also found that the store was selling Pro Active ephedrine products. *Id.* The DI interviewed Green's owner, who told her that twice a week, it purchased twelve boxes of twenty-four Select Brand [s]udafed from Respondent, and that it also purchased 72 boxes of 40 count Pro Active Ephedrine Multi-Action. *Id.* The DI also found that Green's was selling lantern fuel and starting fluid, two products which are used in the illicit manufacture of methamphetamine. *Id.* at 409.

The DI next went to Bart's Package Store, which is also located in Doniphan, Missouri. *Id.* at 410. There, the store owner told the DI that he purchased twelve boxes of Select Brand Pseudoephedrine (24 count) and twelve boxes of Select Brand Antihistamine (24 count) from Respondent every three weeks and sold the products for $7 a box. *Id.* at 412.[5] The DI also found that Bart's sold starting fluid and lantern fuel. *Id.* at 416. According to the father of the owner, initially Bart's had purchased three cans of starting fluid but was then ordering ten cases a week to meet demand. *Id.* at 417–18.

The DI then visited the Country Junction, a convenience store which is also located in Doniphan. *Id.* at 419. There, the DI found that the store was not only purchasing Select Brand sudafed from Respondent, it was also buying Pro Active Multi-Action Ephedrine from another distributor. *Id.* at 419–20.

Next, the DI visited JB's Grocery, in Neelyville. *Id.* at 422. Here again, the DI found that the store was purchasing listed chemical products from both Respondent and another supplier. *Id.* at 423. The store was also selling starting fluid and lantern fuel.[6] *Id.*

On April 5, 2004, after discussing the results of the investigation with her supervisor, the DI called Mr. Marvin Wheeler, who had served as Respondent's contact person during the inspection. *Id.* at 521. The DI told Mr. Wheeler that the office had decided that a ''verbal warning'' would suffice to address Respondent's failure to report the significant loss of list I chemical products, based on the products that were missing during the audit. *Id.* at 521, 531–32. As for Respondent's lack of documentation for its inventory adjustments, the DI ''suggested that they develop a standard procedure to * * * investigate [a] shortage or surplus and document it thoroughly.'' *Id.* at 532.

Later that day, the DI received a telephone call from the same Cape Girardeau based Special Agent informing her that one Keith Frankum had been stopped by local law enforcement officers after leaving Respondent's premises. *Id.* at 356, 435–36. During the stop, which had occurred on April 1, 2004, the authorities found twenty boxes of pseudoephedrine products, an invoice documenting that Respondent had sold the products to Frankum, and a handwritten note which stated: ''Be Careful Leaving here!!'' Gov. Ex. 23. The investigation determined that the note had been written by Jennifer Holloway, the daughter of Respondent's owners who then worked in the customer service department.[7] Tr. 438.

The DI subsequently determined that Frankum had purchased a total of 92 boxes of listed chemical products (58 boxes of Select Brand actifed (24 count) and 34 boxes of Select Brand pseudoephedrine (24 count) on five separate occasions beginning on November 7, 2003, and ending on April 1, 2004. *Id.* at 453–54. According to the testimony of Jane Brotherton, Frankum had called Respondent and specifically asked whether it carried Sudafed and Actifed. *Id.* at 541. Notwithstanding that Frankum's question made her suspicious, *id.*, Frankum was subsequently allowed to purchase these products upon his presentation of a Missouri Retail Sales License which indicated that the location of his business was a storage unit located in Dexter, Missouri. *Id.* at 543; *see also* Resp. Ex. 10.

During Frankum's first visit to Respondent, Ms. Brotherton asked him what type of business he had. Tr. 457. Frankum was vague. *Id.; see also id.* at 548 (testimony of Ms. Brotherton regarding Frankum's third visit; ''there was never any reference to opening up a business''). Moreover, Frankum paid cash for each purchase. *Id.* at 457 & 545; *see also* Resp. Ex. 11, at 1–5.

Even after two other employees who live in Dexter confirmed to Ms. Brotherton that the address given by Frankum was a storage unit, Respondent made additional sales of listed chemical products to him. Tr. 544–47. Moreover, two weeks after Frankum's first purchase, a local police official told Ms. Brotherton that ''Frankum's brother was a meth cook.'' *Id.* at 459, 505. While Ms. Brotherton related this information to other employees, *id.* at 459, she

[4] There were no adjustments to the inventories of the Contac Severe Cold & Flu and BC Allergy Sinus products. *See* Gov. Ex. 22, at 1–2. After adjustments, the shortage in the remaining product, Select Brand Sinus Allergy was reduced by two boxes. *Id.*

[5] According to the DI, several other DEA investigations had found that Bart's had purchased large quantities of listed chemical products from other distributors in the period circa 2000. Tr. 414–15. Most significantly, Bart's had purchased ''over 6 million dosage units from Heartland Distributing for $563,234,'' during a three year period. *Id.* at 415. The DI testified, however, that she did not know whether Bart's had purchased listed chemical products from Respondent during this period. *Id.* at 416. While this testimony is not directly probative of Respondent's conduct, it does support what DEA has found in numerous cases—that non-traditional retailers of listed chemical products are frequently conduits for diversion.

[6] The record indicates that JB's had purchased large quantities of pseudoephedrine from another distributor several years earlier. Tr. 424.

[7] The ALJ also found that ''the record contains no evidence that Jennifer Holloway knew Mr. Frankum, and it is unclear why she passed to note to him.'' ALJ at 21 (FOF 62). According to her mother, when asked why she passed the note, she ''didn't really know.'' Tr. 702. Ultimately, it is not necessary to determine Ms. Holloway's motive to resolve the issues in this case.

apparently never told Respondent's owners about this or any of the sales. *Id.* at 559–60.

Some of Respondent's employees who worked in the customer service department referred to Frankum as ''the drug guy.'' *Id.* at 460; *see also* at 564 (testimony of Jane Brotherton; ''I'm sure the girls that worked up front probably [referred to Frankum as 'the drug guy'] in conversation.''). While Frankum was suspicious enough to prompt Ms. Brotherton to call the local police after his numerous visits, *see* Resp. Ex. 9, Respondent sold listed chemical products to him up until his arrest.

Respondent did not, however, report any of these sales to DEA. Tr. 491. Moreover, during the March 2004 inspection, the DI ''specifically asked [Respondent's liaison] about intelligence information.'' Tr. 491. Even then, Respondent did not mention the sales to the DI. *Id.*

After his arrest, DEA personnel interviewed Frankum. *Id.* at 451–52. Frankum admitted that he had previously been arrested for assault and possession of methamphetamine and stated that ''he did a lot of meth about five years ago.'' *Id.* at 451. Respondent told investigators that he sold the pseudoephedrine products to five main customers, whom he learned of ''through word of mouth''; that pseudoephedrine was a big seller ''because it was used to make drugs''; that ''[h]e didn't think anyone purchased the product for allergies or sinus problems''; and that ''[h]e knew that some of his customers likely used [the] pseudoephedrine that he sold them to make methamphetamine.'' *Id.* at 452–53. Frankum subsequently pled guilty to possession of a methamphetamine precursor drug with intent to manufacture amphetamine, methamphetamine or any of their analogs, a felony offense under Missouri law, and was sentenced to three years of imprisonment. Resp. Ex. 13, at 1.

Upon investigating the circumstances of Respondent's sales to Frankum, DEA investigators re-evaluated their initial position regarding its continued registration and requested that it surrender its registration. Tr. 483–86. Respondent's owner initially agreed to but then changed his mind. *Id.* at 484–85. This proceeding was then initiated.

Respondent's Remedial Measures and Its Policies

The ALJ found that Respondent undertook several corrective actions to prevent diversion following the DEA inspection. These measures included instructing its employees on their obligation to report diversion committed by another employee, Resp. Ex. 18, and the issuance of a written policy which announced that the company was ''limiting the quantity of [Select Brand Sudafed] tablets to 10 each per order and * * * Actifed to 10 each per order.'' Resp. Ex. 20. The policy further stated that employees should ''[a]lso take notice [of] the attached list of items and regulate the quantity of items ordered from it also.'' *Id.* Finally, the policy instructed Respondent's employees to ''[p]lease report any suspicious orders to a manager or Dalton McKnight,'' *id.*, who the company had appointed as its DEA compliance officer. Tr. 480–81. According to the testimony of Respondent's President, the company voluntarily reduced the quantity of products that could be purchased per transaction because he did not ''want to see [the young generation] messed up in this stuff.'' *Id.* at 741.[8]

The ALJ further found that Respondent had reduced the number of listed chemical products it carried from thirty to eighteen and had started a daily inventory of the products. ALJ at 23 (citing Tr. 871–72). Respondent constructed a special cage in which its listed chemical products would be stored under lock; it also limited access to the cage to only three or four supervisory employees. Tr. 881–82. Respondent also adopted the suggestion of the DI that a supervisor fill the listed chemical product orders and created a separate ''pick ticket,'' a document which is used to fill orders and place them on the appropriate truck. *Id.* at 882. Finally, Respondent also issued a memorandum instructing its employees on the proper documenting of all transactions. *See* Resp. Ex. 21.

As found above, the customer verifications indicated that Respondent's customers were also purchasing listed chemical products from other distributors. During his testimony, the Government asked Mr. Holloway whether he aware that J.B.'s Store was purchasing listed chemicals from another distributor. Tr. 774. Mr. Holloway answered that ''none of us would have know[n] that.'' *Id.* at 774–75. Mr. Holloway then added: ''[o]ur salesmen [are] trained to be aware of that. They, you know, you don't get nosy in people's business.'' *Id.* at 775.

The Government then asked Mr. Holloway whether he had ''ever asked any of [his] customer accounts whether they were purchasing listed chemical products from other suppliers?'' *Id.* Mr. Holloway answered: ''[I]n the wholesale world, that's kind of a no-no. If you want [to be] throw[n] out the door * * * if you want your competitor to take [the business], well get too nosy and that's what happens.'' *Id.* When pressed by the Government as to whether his answer was ''no,'' Mr. Holloway explained: ''If the salesman don't want that account, he can go ask personal questions like that and he can lose them.'' *Id.* at 776. Mr. Holloway then added: ''[t]he answer is I taught them, [d]on't lose customers.'' *Id.*

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical ''may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making this determination, Congress directed that I consider the following factors:

(1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

Id. § 823(h).

''These factors are considered in the disjunctive.'' *Joy's Ideas,* 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether a registration should be revoked or an application for a modification of a registration should be denied. *See, e.g., David M. Starr,* 71 FR 39367, 39368 (2006); *Energy Outlet,* 64 FR 14269 (1999). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Based on factors one, two, four and five, I conclude that the Government has

[8] The ALJ also found that Respondent had ''stopped selling Mini-thins in 1999 or 2000,'' another frequently diverted listed chemical product, because the Holloways ''knew it was going to things it shouldn't be going [to],'' ALJ at 23 (quoting Tr. 734), more specifically, the illicit manufacture of methamphetamine. Tr. 734. When asked by his counsel how he learned to this, Mr. Holloway testified: ''you go to the coffee shop, you can learn about everything. It don't mean it always true, but basically, just through hearsay.'' *Id.*

proved that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h). Moreover, having considered the evidence regarding the corrective actions taken by Respondent, I conclude that while some of these measures do adequately address the Agency's concerns, in other respects, they are insufficient to protect the public from the continued diversion of listed chemicals into the illicit manufacture of methamphetamine. Finally, I find wholly unpersuasive—and contrary to the public interest—the ALJ's suggestion that until the diversion of gel caps and liquid pseudoephedrine products is substantiated, I not rely on this ''possibility'' to revoke Respondent's registration. Accordingly, Respondent's registration will be revoked and its pending application will be denied.

Factor One—Maintenance of Effective Controls Against Diversion

As the ALJ noted, DEA precedents establish that this factor encompasses a variety of considerations. ALJ at 31. These include the adequacy of security, the adequacy of record keeping and reporting, the conduct of the registrant and its employees, and the occurrence of diversion. *See Rick's Picks*, 72 FR 18275, 18278 (2007), *John J. Fotinopoulos*, 72 FR 24602, 24605 (2007), *D & S Sales*, 71 FR 37607, 37610 (2006); *Joy's Ideas*, 70 FR 33195, 33197–98 (2005).

As the ALJ found, Respondent constructed a special cage for storing listed chemical products and limited the number of persons with access to it. ALJ at 31. Moreover, the Government did not dispute whether other aspects of Respondent's physical arrangements were adequate. I thus conclude that Respondent provides adequate physical security for its products.

Respondent's recordkeeping is another matter. As the record establishes, the accountability audits showed that there were discrepancies with respect to each of the five audited products. Furthermore, even after the audit took into account Respondent's manual adjustments—which were not supported by appropriate documentation—there were still shortages.[9] While some of the shortages involved small amounts as an absolute matter, they were significant on a percentage basis.

Under DEA regulations, a registrant must have adequate ''systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.'' 21 CFR 1309.71(b)(8). Respondent's lack of documentation for its inventory adjustments supports a finding that its recordkeeping and accountability controls were inadequate. Respondent did, however, implement several changes to its monitoring and record keeping practices. Were there no other evidence of Respondent's inadequate controls, Respondent's corrective actions might well support its being allowed to maintain its registration. There is, however, such evidence.

Jonathan Robbin, the Government's expert witness testified that Respondent's customers are non-traditional retailers of pseudoephedrine products and that the normal expected sales range of these products at Respondent's customers is ''between $ 0 and $ 40 per month[,] with an average of $ 19.85 for pseudoephedrine (HCL) and between $ 0 and $ 20 per month, with an average of $ 8.68'' for its actifed product. Mr. Robbin further testified that ''[a] monthly retail sale of $ 60 of pseudoephedrine (HCL) would be expected to occur less than one in 1,000 times in random sampling,'' and ''[a] monthly retail sale of $ 100 a month of pseudoephedrine (HCL) or of $ 50 of Actifed tablets would be expected to occur about one in a million times in random sampling.'' Gov. Ex. 8, at 8.

Moreover, the Government entered into evidence a rebuttal exhibit prepared by Mr. Robbin which showed that even using Respondent's suggested retail price for Select Brand Sudafed and Actifed,[10] Respondent's customers were still selling these products in extraordinary quantities. More specifically, three stores were selling its sudafed product at ten times expectation; another eight stores were selling the product at five to seven times expectation. As for its actifed product, one store was selling it at over fifty times expectation, seven stores were selling it at twenty-five to fifty times expectation, eleven stores were selling it at ten to twenty-five times expectation, and another eleven stores were selling it at five to ten times expectation.

Respondent attempts to discredit Mr. Robbin's findings by arguing that one of the towns in Respondent's market (Doniphan) is forty miles from a store in the traditional market. This testimony only calls into question Mr. Robbin's findings with respect to the stores in Doniphan. It does not impeach his findings with respect to the other stores or his ultimate finding that Respondent ''frequently has sold products containing pseudoephedrine * * * in extraordinary excess of normal or traditional demand.'' Gov. Ex. 8, at 17–18. Because of the statistical improbability that these sales were to meet legitimate demand, I conclude that a preponderance of the evidence establishes that a substantial portion of Respondent's products have been diverted. *See T. Young*, 71 FR at 60572; see also *D & S Sales*, 71 FR at 37611 (finding diversion occurred ''[g]iven the near impossibility that * * * sales were the result of legitimate demand''); *Joy's Ideas*, 70 FR at 33198 (finding diversion occurred in the absence of ''a plausible explanation in the record for this deviation from the expected norm'').

The ALJ acknowledged that the Government had proved that Respondent had engaged in '' 'grossly excessive sales' of listed chemical products,'' and that ''[i]n the past, this pattern of sales has supported a finding'' of diversion and that Respondent's continued registration ''would be adverse to the public interest.'' ALJ at 40–41. The ALJ noted, however, that ''Respondent ha[d] demonstrated its willingness and its ability to * * * implement changes in its business processes.'' *Id.* In this regard, the ALJ had earlier noted that Respondent had ''voluntarily lowered the maximum number of listed chemical products to be sold per transaction.'' *Id.* at 32.

Respondent's action does not impress me. As the record indicates, Respondent lowered the number of boxes per order from twelve to ten. Tr. 645–46, 653 (testimony of Marvin Wheeler). Moreover, Respondent did not limit the number of times a customer could order in a month; indeed, the record indicates that its customers were allowed to purchase the products twice a week. *Id.* at 654 (testimony of Marvin Wheeler); *see also id.* at 484 (testimony of DI). Even using Respondent's suggested retail price for these products, Respondent's policy would allow a customer to obtain a quantity of products which would sell for approximately $225 per month (actifed) and $146 per month for its sudafed product, amounts which are far in

[9] As found above, one of the manual adjustments was for 105 boxes of Select Brand antihistamine. I do not find Respondent's justification for the discrepancy to be persuasive. For example, if employees were mistakenly pulling this product from the shelf rather than the adjoinign product (Select Brand sudafed), given that both products were audited, one would think that there would be a substantial and corresponding overage in the audit of the actifed. The audit report indicates that there was ony a thirteen box overage on the initial count of the actifed and that after applying Respondent's adjustments, there was a shortage. *See* Gov. Ex. 22, at 1–2

[10] As explained above, Respondent did not produce any evidence that its customers actually sold the products at the suggested retail prices. Indeed, Mr. Holloway testified that under Missouri law, Respondent could not tell its customers what price to sell the products for. TR 783.

excess of the normal expected retail sales by a non-traditional retailer to meet legitimate demand. In short, Respondent's sales limit is not a consequential reform of its business practices and would not prevent diversion.[11] I therefore hold that Respondent does not maintain effective controls against diversion.

Respondent's controls against diversion are inadequate for an additional reason, which the ALJ completely ignored. The record establishes that several of Respondent's customers were receiving listed chemical products from other sources. Yet notwithstanding the potential for diversion of listed chemical products, *see* Tr. 734, Respondent's President and co-owner testified that he had never inquired of his customers as to whether they were purchasing listed chemical products from other distributors. *Id.* at 775–76. Moreover, Mr. Holloway expressed the view that it was inappropriate for his salesmen to ask the firm's customers whether they were purchasing products from other distributors. According to Mr. Holloway, ''[i]f you want [to be] throw[n] out the door * * * if you want your competitor to take [the business], well get too nosy and that's what happens.'' *Id.* at 776. Mr. Holloway further explained that ''[i]f the salesman don't want that account, he can go ask personal questions like that and he can lose them.'' *Id.* Mr. Holloway then stated that he had ''taught'' his sales force, ''[d]on't lose customers.'' *Id.*

Respondent's policy—which is fairly characterized as ''see no evil, hear no evil''—is fundamentally inconsistent with the obligations of a DEA registrant. *See, e.g., D & S Sales*, 71 FR at 37610. As noted in numerous DEA orders, selling amounts below the 1,000 gram threshold that triggers reporting requirements, *see* 21 CFR 1310.04(f), does not create a safe harbor which allows a registrant to distribute listed chemical products in disregard for the ultimate disposition of those products. *See Rick's Picks, L.L.C.*, 72 FR 18275, 18278 (2007); *D & S Sales*, 71 FR 37607, 37609, 37611–12 (2006); *see also United States* v. *Kim*, 449 F.3d 933, 939 (2006). Rather, a registrant has an affirmative duty to protect against diversion by knowing its customers and the nature of their list I chemical sales. Under Federal law, a registrant cannot sell listed chemical products to a customer when it has ''reasonable cause to believe'' the products will be diverted. 21 U.S.C. 841(c)(2). A registrant cannot avoid the requirements of Federal law by instructing its sales force to ask no questions of its customers and thereby be deliberately ignorant of diversion.

I therefore conclude that notwithstanding the corrective measures it has implemented, Respondent still does not maintain effective controls against diversion. Furthermore, this factor, by itself, establishes that Respondent's continued registration is inconsistent with the public interest and provides reason alone to revoke Respondent's registration.

Factor Two and Four—Respondent's Compliance with Applicable Laws and its Past Experience in the Distribution of Listed Chemicals

Under this factor, the ALJ discussed Respondent's failure to report to DEA its transactions with Mr. Frankum notwithstanding their suspicious nature. *See* ALJ at 34. The ALJ did not, however, make any finding as to whether Respondent had in fact violated federal law because it reported the transactions to local authorities rather than DEA. *See id.*

The Government offers no argument as to why Respondent's failure to report these transactions to DEA violated federal law. *See* Gov. Proposed Findings and Conclusions of Law at 44. In any event, the real issue is not Respondent's failure to report the transactions but its repeated sales to Mr. Frankum given the information it had obtained.

It is a violation of federal law for ''[a]ny person [to] knowing or intentionally * * * distribute[] a listed chemical * * * having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by'' the CSA. 21 U.S.C. 841(c)(2). Moreover, ''[t]here is no quantity threshold exempting a merchant from criminal liability under § 841(c)(2).'' *Kim,* 449 F.3d at 941.

The record clearly establishes that Respondent's employees with requisite authority had knowledge of facts which created ''reasonable cause to believe'' that the pseudoephedrine products it sold to Frankum would be used to manufacture methamphetamine. *United States* v. *Kaur*, 382 F.3d 1155, 1158 (9th Cir. 2004) (defining standard as whether defendant actually ''knew, or knew facts that would have made a reasonable person aware, that the pseudoephedrine would be used to make methamphetamine'').

As found above, when Frankum first contacted Respondent, he specifically asked Ms. Brotherton whether the firm sold Actifed and Sudafed. Moreover, when Frankum visited Respondent, the sales tax certificate which he presented gave a storage unit as his business's address and when interviewed, Frankum was vague about the nature of his business. Furthermore, Frankum did not complete a credit application, but rather paid cash for his purchases. *See* U.S. Dept. of Justice, *Report to the U.S. Attorney General by the Suspicious Order Task Force,* Appendix A (1999).

The record further establishes that within two weeks of Frankum's first visit, Officer Clark informed Ms. Brotherton that Frankum's brother was a ''meth cook.'' Tr. 459, 505. Moreover, Respondent's employees referred to Frankum as ''the drug guy.'' *Id.* at 460. Finally, Ms. Brotherton testified that even during Frankum's third visit, ''there was never any reference to opening up a business.'' *Id.* at 548.

I thus conclude that Respondent knowingly distributed listed chemical products to Frankum having reasonable cause to believe that the products would be used to manufacture methamphetamine. While the information Ms. Brotherton initially obtained may not have risen to the level of ''reasonable cause,'' having been told by law enforcement authorities that Frankum's brother was ''a meth cook,'' and Frankum's continued vagueness about the nature of his business, did establish reasonable cause.[12] Furthermore, Respondent does not contend that the acts of Ms. Brotherton or the other employees involved in the transactions were unauthorized or were not undertaken for the corporation's benefit. *See, e.g., United States* v. *Basic Construction Co.,* 711 F.2d 570, 573 (4th Cir. 1983); *United States* v. *Cincotta*, 689 F.2d 238, 241–42 (1st Cir. 1982); *see also United States* v. *Bank of New England*, 821 F.2d 844, 856 (1st Cir. 1987) (''[T]he knowledge obtained by corporate employees acting within the

[11] It is acknowledged that this discussion involves products in tablet form that Respondent can no longer distribute under Missouri law. However, once the Government proved that Respondent's products have been diverted, the burden of proof shifted to Respondent to show that its controls were adequate. *See Gregory D. Owens,* 67 FR 50461, 50464 (2002); *Thomas Johnston*, 45 FR 72311 (1980). Furthermore, this hearing took place eight months after Missouri changed its law.

Respondent's memorandum instituting the sales limit vaguely instructed its employees to ''take notice to the attached list of items and regulate the quantity of items ordered from it also.'' Resp. Ex. 20, at 1. It is thus far from clear what limits Respondent has imposed on its sales of gelcap and liquid products. It was, however, Respondent's burden to show that its controls were adequate and that the sales limits it imposed would prevent diversion of its gel cap and liquid products. This it failed to do.

[12] To establish a violation of this provision, the Government is not required to prove that the products were actually used to manufacture methamphetamine. *See United States* v. *Johal,* 428 F.3d 823, 828 (9th Cir. 2005); *United States* v. *Prather*, 205 F.3d 1265, 1269–70 (11th Cir. 2000).

scope of their employment is imputed to the corporation.''). Accordingly, the violations involving the Frankum sales are properly charged to Respondent.

I acknowledge that Ms. Brotherton reported the Frankum sales to local authorities and that Frankum was eventually arrested and pled guilty to the state law offense of possession of a methamphetamine precursor with intent to manufacture. But Respondent should never have sold listed chemicals to Frankum in the first place. I thus find that Respondent violated federal law at least three times when it sold pseudoephedrine products to Frankum. While I acknowledge that Respondent appears to have implemented a training program that addresses the Frankum incidents, I nonetheless conclude that Respondent's record of compliance with applicable laws and its experience in distributing listed chemicals support a finding that its continued registration is inconsistent with the public interest.[13]

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

The illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation. This is especially so in Missouri which, notwithstanding the State's enactment of a law restricting the sale of certain pseudoephedrine products, still has an extraordinarily serious problem with illicit methamphetamine production and its abuse. *See* Gov. Ex. 28. As the record demonstrates, while the Missouri law has led to a substantial reduction in the number of meth. lab seizures, law enforcement authorities still seized 745 illegal labs in the latter half of 2005. The illicit production of methamphetamine thus remains a grave threat to public health and safety in Missouri. Cutting off the supply source of methamphetamine traffickers is of critical importance in protecting the citizens of Missouri and adjoining States from the devastation wreaked by this drug.

While listed chemical products containing pseudoephedrine have legitimate medical uses, both DEA orders and the record here establish that convenience stores and gas-stations constitute the non-traditional retail market for legitimate consumers of products containing these chemicals. *See, e.g., Tri-County Bait Distributors,* 71 FR 52160, 52161–62 (2006); *D & S Sales,* 71 FR at 37609; *Branex, Inc.,* 69 FR 8682, 8690–92 (2004). DEA has further found that there is a substantial risk of diversion of list I chemicals into the illicit manufacture of methamphetamine when these products are sold by non-traditional retailers. *See, e.g., Joy's Ideas,* 70 FR at 33199 (finding that the risk of diversion was ''real'' and ''substantial''); *Jay Enterprises, Inc.,* 70 FR 24620, 24621 (2005) (noting ''heightened risk of diversion'' if application to distribute to non-traditional retailers was granted).

Accordingly, ''[w]hile there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to [gas stations and convenience stores], DEA has nevertheless found that [these entities] constitute sources for the diversion of listed chemical products.'' *Joey Enterprises, Inc.,* 70 FR 76866, 76867 (2005). *See also TNT Distributors,* 70 FR 12729, 12730 (2005) (special agent testified that ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores'').[14] Here, the record establishes that several of the stores that Respondent supplied had previously been found to be purchasing extraordinary quantities of listed chemicals. *See* Tr. 414–15, 424–25 (discussing purchases of Bart's and JB's).

Moreover, as found above under factor one, the evidence supports a finding that Respondent supplied numerous non-traditional retailers with listed chemical products and that it sold extraordinary quantities of these products to a substantial number of these establishments. The evidence thus also establishes that a substantial portion of Respondent's products have been diverted.[15]

The ALJ also noted that Respondent's List I chemical sales are a ''minute percentage of [its] total business,'' and stand in ''contrast to other revocation cases, where * * * List I chemicals products have represented a significant portion of business.'' ALJ at 39 (citations omitted). Be that as it may, even where List I products are a ''minute percentage'' of a registrant's total business, a substantial amount of products can still be diverted, especially where, as here, a registrant lacks effective controls to prevent diversion. *See* discussion of factor one.

Finally, while the ALJ acknowledged that some methamphetamine traffickers ''have already begun to circumvent the new [Missouri] law'' by using liquid and gelcap forms of pseudoephedrine, ALJ at 39, the ALJ concluded that the law ''drastically reduce[s] the potential for diversion and harm to public safety.'' *Id.* at 40. The ALJ further explained that ''the State will be monitoring the gelcap and liquid pseudoephedrine products, if any, found in the methamphetamine labs. Such heightened scrutiny leads to the conclusion that, if the products of the Respondent, as well as other distributors of List I chemical products in Missouri, are found in illicit methamphetamine laboratories, the State will close the legislative loophole afforded these limited products.'' *Id.* at 41. The ALJ then reasoned that ''[u]ntil such time as the problem is substantiated * * * I recommend that the possibility of the Respondent's products being diverted not be relied upon to revoke * * * Respondent's Certificate of Registration.'' *Id.*

In *T. Young Associates,* an Order published before the issuance of the recommended decision in this matter, I rejected a similar argument. *See* 71 FR at 60573. There, I noted several studies (including those by the Washington State Patrol and McNeil Consumer and Specialty Pharmaceuticals) which show ''that methamphetamine can be produced from List I chemicals sold as liquid-filled gelcaps and liquids.'' *Id.* (citing DEA, *Microgram Bulletin* 96–97, 102 (June 2005)). Here, the record likewise establishes that pseudoephedrine ''can be easily extracted'' from gelcaps and liquid products using ''readily available'' reagents and solvents. Gov. Ex. 4, at 8.

Contrary to the ALJ's understanding, the diversion of gelcap and liquid forms of pseudoephedrine into the illicit manufacture of methamphetamine has already been ''substantiated.'' *See* Gov. Ex. 7, Tr. 87–88, 91 Moreover, as I noted

[13] I acknowledge that Respondent has not been convicted of a criminal offense. The actual conduct of Respondent, however, outweighs the fact that it has not been charged and convicted of a criminal offense.

[14] *See OTC Distribution Co.,* 68 FR 70538, 70541 (2003) (noting ''over 20 different seizures of [gray market distributor's] pseudoephedrine product at clandestine sites,'' and that in eight-month period distributor's product ''was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone.''); *MDI Pharmaceuticals,* 68 FR 4233, 4236 (2003) (finding that ''pseudoephedrine products distributed by [gray market distributor] have been uncovered at numerous clandestine methamphetamine settings throughout the United States and/or discovered in the possession of individuals apparently involved in the illicit manufacture of methamphetamine'').

[15] While the ALJ concluded ''that diversion is the only conceivable explanation'' for Respondent's excessive sales, she further reasoned that Respondent may have been less likely to detect these sales because of its large customer base. ALJ at 38–39. Respondent itself did not make this argument and thus it need not be considered. In any event, DEA case law establishes that a registration can be revoked even when a registrant was ''an unknowing and unintentional contributor to [the] methamphetamine problem.'' *Joy's Ideas,* 70 FR at 33198. *See also T. Young,* 71 FR at 60572.

in *T. Young*, ''experience has taught DEA that in the aftermath of every major piece of legislation addressing the illicit manufacture of methamphetamine, traffickers have quickly found ways to circumvent the restrictions.'' 71 FR at 60573; *see also* Tr. 63–64. This Agency is not required to wait until the diversion of gelcap and liquid forms of pseudoephedrine reaches epidemic proportions before acting to protect the public interest. Therefore, I reject the ALJ's finding that factor five supports the continuation of Respondent's registration.[16]

In conclusion, the record establishes that Respondent's products have been diverted. While Respondent has taken corrective actions, these measures are still not adequate to protect against the diversion of its products. Furthermore, Respondent violated federal law by knowingly distributing listed chemical products when it had reasonable cause to believe that the products would be used to manufacture methamphetamine. Finally, studies show that pseudoephedrine can be easily extracted from gelcap and liquid forms of pseudoephedrine and anecdotal evidence establishes that methamphetamine traffickers are already using these products. Factor five does not require that DEA wait until the diversion of these products becomes widespread before acting to protect the public interest. Therefore, I conclude that Respondent's continued registration is ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) 7 0.104, I order that DEA Certificate of Registration, 003219HIY, issued to Holloway Distributing, Inc., be, and it hereby is, revoked. I further order that the pending application of Holloway Distributing, Inc., for renewal of its registration, be, and it hereby is, denied. This order is effective August 31, 2007.

Dated: July 20, 2007.

Michele M. Leonhart,

Deputy Administrator.

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[16] In her analysis of factor five, the ALJ concluded that the Government had not proved that ''Respondent's continued distribution of liquid and gelcap forms of List I chemical products poses a threat to the public health and safety.'' ALJ at 40. The ALJ erred, however, because she applied the wrong legal standard.

As I have previously explained, the Government is not required to prove that Respondent's conduct poses a threat to public health and safety to obtain an adverse finding under factor five. *See T. Young,* 71 FR at 60572 n.13. Rather, the statutory text directs the consideration of ''such other factors as are relevant to and consistent with the public health and safety.'' 21 U.S.C. § 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. *See id.* § 823(f)(5) (directing consideration of ''[s]uch other conduct which may threaten the public health and safety'').

Accordingly, while proof of a threat to public health and safety clearly satisfies the standard of subsection 823(h)(5), it is not required. Distributing a product, which studies show can be easily used to make methamphetamine, clearly satisfies this standard even in the absence of evidence showing widespread diversion of the products.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07–23]

Newcare Home Health Services; Revocation of Registration

On February 21, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Newcare Home Health Services (Respondent), of Baltimore, Maryland. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BN3795892, as a retail pharmacy, on the ground that the Maryland State Board of Pharmacy had suspended Respondent's state pharmacy license.[1] *See id.*

On or about February 23, 2007, the Show Cause Order was served on Respondent. On March 9, 2007, Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who, on March 15, 2007, ordered the parties to file pre-hearing statements.

On March 19, 2007, the Government moved for summary disposition and to stay the filing of pre-hearing statements. The basis for the Government's motion was that on January 5, 2007, the Maryland Board of Pharmacy had summarily suspended Respondent's state pharmacy and distributor permits. Mot. for Summ. Disp. at 2. In support of its motion, the Government attached a copy of the Maryland Board's Order for Summary Suspension. Upon receipt of the motion, the ALJ granted the Government's motion to stay the proceeding and ordered Respondent to reply to the motion for summary disposition. See Order Staying Proceedings at 1–2.

On March 29, 2007, Respondent submitted its reply. Respondent acknowledged that summary disposition would be appropriate but asked the ALJ ''to stay all proceedings * * * while the criminal prosecution of [its] owners proceeds through the U.S. District Court.'' Resp.'s Reply at 1. Respondent further argued that ''[i]f the outcome of the criminal case is favorable to [its] owners, then the posture and merits of this matter * * * will be substantially different than if one or more convictions are obtained.'' *Id.* at 2. Respondent further stated that it had appealed the State Board's suspension of its pharmacy license and had ''asked the Board to defer any hearing on the appeal until the criminal case concludes.'' *Id.* Respondent further stated that it would agree to the suspension of its registration in the interim. *Id.*

On April 3, 2007, the ALJ issued her recommended decision. Noting that state authority is ''a prerequisite to DEA registration,'' the ALJ held that Respondent was not entitled to maintain its registration because there was no dispute that Respondent currently lacks ''authority to handle controlled substances in the jurisdiction where it seeks to maintain its DEA registration.'' ALJ at 4. The ALJ also denied Respondent's request for a stay. The ALJ thus granted the Government's motion for summary disposition, lifted her stay order, and denied Respondent's request for a continued stay of the proceeding. The ALJ also recommended that Respondent's registration be revoked and forwarded the record to me for final agency action.

Having considered the record as a whole, I adopt the ALJ's decision and recommended order in its entirety. As the ALJ found, Respondent does not currently possess authority under the laws of Maryland to handle controlled substances.

Under the Controlled Substances Act (CSA), ''a practitioner must be currently authorized to handle controlled substances in 'the jurisdiction in which [it] practices' in order to maintain its DEA registration.'' *Bourne Pharmacy, Inc.*, 72 FR 18273, 18274 (2007) (quoting 21 U.S.C. 802(21)). *See also* 21 U.S.C. 802(21) (''[t]he term 'practitioner' means a * * * pharmacy * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which [it]

[1] The Show Cause Order also alleged that Respondent had committed acts which rendered its registration ''inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)). More specifically, the Show Cause Order alleged that Respondent ''illegally distributed vast quantities of hydrocodone and other controlled substances'' by filling prescriptions that were issued over the internet and which were issued by physicians who did not establish ''a doctor-patient relationship with the customers.'' Id. In light of the disposition of this case, a more detailed recitation of the allegations of the Show Cause Order is not necessary.