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Maureen Katz,

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

[FR Doc. 2010–11947 Filed 5–18–10; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Proposed Consent Decree and Proposed Order on Consent Under The Clean Water Act

Notice is hereby given that, on May 12, 2010, a proposed Consent Decree in *United States and State of New York* v. *City of Oswego, New York,* Civil Action No. 5:10–cv–554, was lodged with the United States District Court for the Northern District of New York.

The proposed Consent Decree will settle the United States' claims on behalf of the U.S. Environmental Protection Agency ("EPA") for violations of Section 301(a) of the CWA, 33 U.S.C. 1311(a), in connection with unpermitted discharges from the City's west side sewer system and failure to comply with a National Pollutant Discharge Elimination System ("NPDES") permit. The State of New York joined the United States as co-plaintiff, pursuant to Section 309(e) of the CWA, 33 U.S.C. 1319(e), and the New York State Environmental Conservation Law ("ECL"), Sections 17–0701 and 17–0803. The Consent Decree resolves all claims in the Complaint, in return for payment by the City of a civil penalty of $99,000, to be split evenly between the United States and the State, and performance by the City of corrective actions valued at $87 million.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of 30 days from the date of this publication. Comments on the Consent Decree should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States and State of New York* v. *City of Oswego, New York,* Civil Action No. 5:10–cv–554 (N.D.N.Y.), D.J. Ref. No. 90–5–1–1–08609.

The proposed Consent Decree may be examined at the Office of the United States Attorney, Northern District of New York, 100 South Clinton Street, Syracuse, New York 13261, and at EPA, Region 2, 290 Broadway, New York, New York 10007–1866. During the public comment period, the proposed Consent Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax number (202) 514–0097, phone number (202) 514–1547. If requesting a copy by mail from the Consent Decree Library, please enclose a check in the amount of $18.50 ($0.25 per page reproduction cost) payable to the United States Treasury or, if requesting by e-mail or fax, forward the check in that amount to the Consent Decree Library at the address stated above. If requesting a copy exclusive of appendices, please enclose a check in the amount of $16.00 ($0.25 per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

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

[FR Doc. 2010–11948 Filed 5–18–10; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06–55]

M & N Distributors; Dismissal of Proceeding

On March 16, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to M & N Distributors (Respondent), of Springfield, Tennessee. The Order to Show Cause proposed the revocation of Respondent's DEA Certificate of Registration as a distributor of list I chemicals on the ground that its continued registration "is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h)." Order to Show Cause at 1.

More specifically, the Show Cause Order made three major allegations against Respondent. First, it alleged that on November 22, 2005, Agency Investigators performed an accountability audit of Respondent's handling of three listed-chemical products and found an overage of "732 bottles (more than five cases) of one 36-count combination ephedrine product." *Id.* at 2. Next, the Show Cause Order alleged that in June 2003, Respondent "reported a loss of a case of 144 bottles of ephedrine, which [Respondent] indicated fell out the back door of his truck" and that "this product was never recovered." *Id.*

Finally, the Show Cause Order alleged that between 2001 and 2005, DEA retained an expert "in the field of retail marketing and statistics" "to analyze national sales data for over-the-counter non-prescription drugs" and that based on his "study of hundreds of Tennessee retailers," the expert had concluded "that these retail stores had made purchases of listed chemical products far in excess of amounts of product that could be reasonably sold for legitimate purposes in stores of these [sic] kind in Tennessee." *Id.* at 3. The Order further alleged that "DEA has observed that many smaller or non-traditional stores, such as * * * gas stations [ ] and some small markets, purchase inordinate amounts of these products and become conduits for the diversion of listed chemical[s] into illicit drug manufacturing." *Id.* Because Respondent's owner "told investigators that he had approximately 120 convenience store and gas station customers located in Tennessee and Kentucky," *id.* at 2, the Order implied, without ever expressly alleging, that Respondent sold listed chemical products "far in excess of amounts of product that could be reasonably sold for legitimate purposes." *Id.* at 3.[1]

On April 5, 2006, Respondent's owner, Charles Ramsey, requested a hearing on the allegations and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJ). ALJ Ex. 2. Thereafter, on June 5, 2006, Counsel for Respondent entered his appearance, ALJ Ex. 3, and following pre-hearing procedures, a hearing was held before an ALJ in Nashville, Tennessee on August 23 and 24, 2006. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed briefs containing their proposed findings, conclusions of law, and argument.

On December 16, 2008, the ALJ issued her Recommended Decision. Therein, the ALJ concluded that the Government had not proved that the continuation of

[1] In her Decision, the Administrative Law Judge (ALJ) formulated the issue as "whether the Respondent sold quantities of listed chemical product which it knew, or should have known, exceeded quantities that could be sold by its customers for legitimate use." ALJ at 31 (citing Gov't Br. at 9).

Respondent's registration would be inconsistent with the public interest. ALJ at 42. With respect to factor one—the maintenance of effective controls against diversion—the ALJ found that Respondent provided adequate security for the listed chemical products it distributed, and that while Respondent had once lost a case of a product (three years earlier), he had reported the loss and taken corrective action to prevent a reoccurrence. *Id.* at 29. With respect to Respondent's recordkeeping, the ALJ found unproven the Government's contention that its audit of Respondent's handling of three products had found that it had an overage of 732 bottles of one product. *Id.* at 30. The ALJ further found, however, that Respondent's "perpetual inventory logs * * * are difficult to decipher" and "that at least one of the log pages does not include the name of the product it purports to track." *Id.* at 29–30. The ALJ nonetheless concluded that Respondent maintains effective controls against diversion and that this factor supported its continued registration. *Id.* at 30.

As to factor two—Respondent's compliance with applicable Federal, State and local law—the ALJ noted that the record contained no direct evidence of violations of such laws. *Id.* Similarly, as to factor three—Respondent's record of convictions for offenses related to controlled substance or listed chemicals—the ALJ noted that neither Respondent, nor its owner, has been convicted of a crime related to the handling of listed chemical products. *Id.* at 31. The ALJ thus found that both factors two and three supported Respondent's continued registration. *Id.*

As to factor four—Respondent's past experience in the distribution of listed chemicals—the ALJ framed the issue as whether Respondent had sold "quantities of listed chemical products which it knew, or should have known, exceeded quantities that could be sold by its customers for legitimate use." *Id.* Noting that the Government's proof was based on two affidavits of an expert witness whose methodology was subsequently founding wanting (at least with respect to combination ephedrine products) in a subsequent case (*Novelty Distributors,* 73 FR 52689 (2008)), ALJ at 33–34, and that these affidavits contained "numerous opinions without stating the bases for those opinions," *id.* at 35, as well as inconsistencies between their conclusions, *id.* at 35–36, the ALJ found that the Government had not established a valid baseline for average monthly sales per store and therefore had not shown that "Respondent sold listed chemical products in amounts sufficient to support an inference of diversion." *Id.* at 38. The ALJ thus concluded that "this factor does not weigh against the continuation of * * * Respondent's registration." *Id.* at 39.

As to the final factor—other factors relevant to, and consistent with, the public health and safety—the ALJ noted that "the Government has failed to prove by a preponderance of the evidence that Respondent engaged in excessive sales or created a serious risk of diversion in its handling of listed chemical products." *Id.* at 41. The ALJ further explained that "Respondent's sales alone do not lead to the conclusion that continuing * * * Respondent's registration would create a substantial risk to the public health and safety." *Id.*

The ALJ thus concluded that the Government had failed to meet "its burden of proof in showing that the Respondent's continued registration would be against the public interest." *Id.* at 42. Nonetheless, while acknowledging that Respondent's perpetual inventory log "exceeded the DEA's recordkeeping practices," because "the incomplete and illegible nature of some of its logs render an accurate assessment of its accountability extremely difficult," the ALJ recommended that I "admonish * * * Respondent to improve its recordkeeping." *Id.* at 42–43. The ALJ further recommended that Respondent's registration be continued subject to three conditions: (1) That it is only authorized to distribute soft gel products; (2) that it improve its recordkeeping so that its sales records are "clearly legible," and that both "the product sold" and the customer are "clearly identified"; and (3) that for a period of one year, Respondent consent to inspections "based on a Notice of Inspection rather than an Administrative Inspection Warrant." *Id.* at 43.

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the entire record in this matter, I adopt the ALJ's conclusions of law with respect to each of the statutory factors except for the following: The final paragraph of her discussion of factor four, which suggests that a registrant cannot be charged with knowledge that its products were being diverted based on its sales levels unless the Agency publishes a regulation or provides "other information" to the registrant, as well as her discussion to the effect that the Government must show, through "direct evidence * * * that methamphetamine has *actually* been made in an illicit methamphetamine laboratory from soft gel listed chemical products" to sustain a finding that the continuation of a registration is inconsistent with the public interest. ALJ at 42. Finally, while I agree with the ALJ that the Government has not established that Respondent's continued registration is inconsistent with the public interest, *id.* at 43, I further conclude that the conditions she recommended are not supported by the record. *Id.* I make the following findings.

Findings

Both pseudoephedrine and ephedrine are lawfully marketed as non-prescription drug products under the Food, Drug and Cosmetic Act. GX 13, at 3–4. Pseudoephedrine is approved for marketing as a decongestant; ephedrine (in combination with guaifenesin) is approved for marketing as a bronchodilator. *Id.* Both chemicals are, however, regulated as list I chemicals under the Controlled Substances Act (CSA) because they are precursor chemicals that are extractable from non-prescription drug products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. *Id.* at 7–8; *see also* 21 U.S.C. 802(34)(C) & (K); 21 CFR 1308.12(d).

Respondent is a wholesale distributor of items such as lighters, tobacco products, toys, sunglasses, hats, and list I chemical products which include pseudoephedrine and ephedrine. Tr. 310. Mr. Charles Ramsey has owned the business since 1980 and is its sole owner and employee.[2] *Id.* at 309. Mr. Ramsey operates Respondent from his residence in Springfield, Tennessee, which is also its DEA-registered location. *Id.* at 316; GXs 23 & 24.

Respondent has held a DEA registration to distribute list I chemicals since June 17, 1999. ALJ Ex. 12. Respondent's current certificate of registration was to expire on January 31, 2007. RX 6. However, on December 12, 2006, Respondent filed a renewal application. ALJ Ex. 12. In accordance with the Administrative Procedure Act and DEA regulations, I find that Respondent's registration has remained in effect pending the issuance of this Final Order. 5 U.S.C. 558(c); 21 CFR 1309.45.

As of the hearing, Respondent had approximately 120 customers, the majority of which were convenience stores and grocery stores. Tr. 311–12, 398. Respondent carried single-dosage

[2] Mr. Ramsey has never been convicted of a crime under State or Federal law related to the handling of listed chemical products or controlled substances; nor has anyone residing in his residence been convicted of such a crime. Tr. 320.

packages of Dayquil Sinus, which contains pseudoephedrine, and six-count and twelve-count boxes of Rapid Action, a product which combines 25 milligrams of ephedrine with guaifenesin. *Id.* at 310–11. However, prior to passage of the Tennessee Meth Free Act ("the Act") in 2005, Respondent distributed 36-count bottles of Rapid Action. *Id.* at 311. In addition, Respondent previously carried the ephedrine products BronchEze and Twin Tab. *Id.* Since the passage of the Act, Respondent has sold list I gel-cap, or "liquid," products to its Tennessee customers in a twelve-count blister box or a six-counter blister pack. *Id.* at 311–12, 351–53; RX 1.

List I chemical products represented less than ten percent of Respondent's gross sales in 2004; of its estimated gross sales of $300,000, approximately $20,000 to $25,000 came from sales of list I chemical products. *Id.* at 399. Subsequent to passage of the Act, Respondent's sales of ephedrine products decreased but remained its single largest selling product. *Id.* at 399–400.[3]

On May 24, 2003, Respondent reported to DEA that three days earlier, he had lost a case (144 bottles) of sixty-count Max Brand Two Way, a combination ephedrine product. GX 24. Respondent submitted the report on the appropriate form and attached a separate letter which explained the circumstances of the loss,[4] how he discovered it, and the efforts he had undertaken to find the lost product. *Id.* at 3. Respondent further explained the corrective action he had taken to prevent a reoccurrence. *Id.* at 1. Respondent also explained that he did not report the incident to the local sheriff because he did not believe that the products had been stolen.[5] *Id.* at 3. Respondent had not experienced any further losses up through the date of the hearing. Tr. 346; ALJ at 8.

On November 22, 2005, two DEA Diversion Investigators (DIs) went to Respondent's registered location to conduct an inspection. Tr. 139–40. The DIs met with Mr. Ramsey and presented him with a Notice of Inspection. *Id.* at 141. The DIs questioned Mr. Ramsey about the nature of his business, inspected the physical security (which was clearly adequate[6]), and examined his records. *Id.* at 140–45. The DIs also told Mr. Ramsey that they would be doing an audit; the DIs thus took an inventory of the listed chemical products he had on hand (which Mr. Ramsey agreed with), which was to be used as the closing inventory. The DIs also obtained copies of his records which included his purchase invoices and a "perpetual inventory"; the latter provided a running list of sales of each product by date, store, quantity, and invoice number. *Id.* at 141, 145–46, 149–53; GX 22; RX 4.

To perform the audit, the DI used January 1, 2005 as the starting date; because Respondent did not then have any products on hand, he assigned a value of zero for each of the products. Tr. 151–52; GX 22, at 2. Based on his review of Respondent's invoices documenting its purchases from its suppliers, which was added to the zero opening inventory figure for each product, the DI calculated the total amount of each product for which Respondent was accountable and entered the figures on the Computation Chart.[7] Tr. 152–54; GX 23. The DI also reviewed Respondent's perpetual inventory to calculate its sales of listed chemical products and added these figures to the closing inventory to calculate the total amount that Respondent could account for. Tr. 145, 153–54; RX 3.

The DI then compared the figures for each of the three products. GX 23. While the audit found that two of the products balanced, the audit found an overage of 732 bottles of the 36-count Rapid Action Ephedrine 2-Way product. *Id.* According to the DI, "in theory" this suggests that Respondent had distributed 732 more bottles than it purchased. However, because this is not possible, such an overage could result from a delivery of product with no invoice from its supplier, a lost invoice, or mistaken documentation such as recording the sale of one product as a different product. Tr. 154–55.

Mr. Ramsey disputed the accuracy of the audit. While he agreed with the DI's figures for Respondent's purchases of Rapid Action bottles and the closing inventory, Mr. Ramsey maintained that when he attempted to recreate the Government's audit, his results did not match. Tr. 326, 334, 357, 367; *see also* GX 23. According to Mr. Ramsey, his total amount of the distributions during the audit period was 11,328 bottles and not the DI's figure of 12,048 bottles. Tr. 367–71. Moreover, his figure for the "Total List I accounted for" was just 12,240 bottles and not 12,972 as the DI had found. Tr. 328; *see also* GX 23.

In his testimony, Mr. Respondent suggested several reasons for why the DI found the overage. Tr. 329–33. First, Mr. Ramsey claimed that the DI had apparently not accounted for a return of twelve bottles, which reduced the discrepancy in the results from 732 to just 720 bottles. *Id., see also* RX 4, at 4 (invoice documenting return of twelve bottles). As for the remaining 720-bottle overage, Mr. Ramsey suggested two explanations. First, that the DI could have erroneously added in 720 bottles of BronchEze to the total amount of the distributions. Tr. 332; *see also* RX 3, at 25 (listing sales of BronchEze during July 2005).[8] Second, that the DI could have erroneously added in two other distributions it received (for 288

[3] The ALJ found that the Government produced no evidence that any list I chemical products distributed by Respondent have been found at illicit methamphetamine laboratories or that the particular brands of soft-gel listed chemical products distributed by Respondent were either discovered at an illicit methamphetamine laboratory or successfully used to produce methamphetamine. ALJ at 12 (citing Tr. 37, 46–48, 50 & 52); *see also id.* at 29 & 42. Related to the latter point, a DEA Special Agent testified that since 2005, law enforcement authorities have discovered more than 400 illicit methamphetamine laboratories in southeastern Tennessee alone and that gel-cap listed chemical products were found in very few of these labs, with the majority using tablet-form products. Tr. 46–48.

That there is no evidence linking products sold by Respondent to illicit meth. labs does not, however, foreclose the Agency from evaluating the adequacy of its diversion controls, its compliance record, and other factors relevant in the public interest inquiry. As for the evidence regarding the use of gel caps, the hearing in this matter was held in August 2006. Given that tablet-form products were available in Tennessee until May of 2005, as well as in adjacent States until the passage of the Combat Methamphetamine Epidemic Act in 2006, it is possible that traffickers bought up as much tablet-form product as possible before this form was banned, and that those supplies were still being used.

[4] Respondent explained that the product had been stored on the back of his truck and that the door to the truck's cargo area had become unlatched. GX 24.

[5] There is a factual dispute as to whether Mr. Ramsey provided oral notification of the loss to DEA. *Compare* Tr. 156 (testimony of DI that while he was not in the office then, he checked with his co-workers and that none of them "can remember a phone call being received from Mr. Ramsey"), *with id.* at 345 (Mr. Ramsey's testimony that he called DEA). The ALJ did not clearly resolve this factual dispute, which is material because DEA's regulation requires both an oral and written report. *See* ALJ at 7.

[6] Mr. Ramsey stores his listed chemical inventory at his registered location in a separate, secure room with a locked door, which has an ADT security system monitor. *Id.* at 317–19; RX 2, at 1, 6. Within that room, the listed chemical products are stored in a 30-gauge steel cage with welded hinges and padlocks. Tr. 317–20. Only Mr. Ramsey has access to the keys to the cage, which he stores in a combination-locked safe. *Id.* at 319; RX 2, at 3. In Mr. Ramsey's twenty-seven year residence on the property, he has not experienced a single theft or break-in. Tr. 319. Finally, Mr. Ramsey does not stored listed chemical products on his delivery trucks overnight but instead returns them to the cage. *Id.* at 320.

[7] According to the computation chart, credits and returns (presumably to suppliers) were to be counted in determining the total amount of product Respondent was accountable for. GX 23. For each product, the chart indicates that the amount of both the credits and returns was zero.

[8] It is undisputed that this document was among those taken by the Government. Tr. 331.

BronchEze and 432 Twin Tabs) to the total amount. *Id.* at 332–33; RX 3, at 39, 45.

Although it bears the burden of proof, the Government offered no evidence (such as an accounting showing each distribution it included in calculating the overage) to rebut Mr. Ramsey's contentions.[9] Moreover, having conducted my own review of Respondent's records, I agree with Mr. Ramsey's figure for the total amount of Rapid Action that he distributed. I further conclude that, at most (and even this is doubtful), twelve bottles are unaccounted for. Consequently, I agree with the ALJ that the Government failed to prove by a preponderance of the evidence that the audit revealed a 732-bottle overage for the Rapid Action product.

As noted above, the Government also apparently alleged that Respondent was selling listed chemical products to convenience stores and gas stations in quantities that were "far in excess of [the] amounts of product that could be reasonably sold for legitimate purposes." Show Cause Order at 3. In support of the allegation, the Government introduced two affidavits prepared by an expert witness for proceedings involving two different distributors. *See* GXs 20 & 27. The gist of these affidavits was that the normal expected retail sale of pseudoephedrine in a convenience store is between $10 and $30 a month, with an average of $20 per month, and that a sale of more $100 a month (to meet legitimate demand) could be expected to occur "about once in a million raised to the tenth power." GX 20, at 8–9. The affidavit further asserts that the normal expected sales level of combination ephedrine products at "a convenience store is about one quarter that of single ingredient products." *Id.* at 11.

Subsequent to the closing of the record in this proceeding, I found that the expert's methodology was unreliable for several reasons. *See Novelty Distributors, Inc.,* 73 FR 52689, 52693–94 (2008). I further concluded that the Expert's testimony as to the normal expected sales range of the products and statistical probability that various sales levels were consistent with legitimate demand did not constitute substantial evidence. *Id.* at 52694. As I have previously held, even when a Respondent has not raised similar challenges to the Expert's methodology, the Agency cannot ignore the ultimate finding in Novelty that the expert's conclusions as to the expected sales levels (and probabilities) do not satisfy the substantial evidence test. *See CBS Wholesale,* 74 FR 36746, 36748 (2009); *Gregg & Son Distributors,* 74 FR 17517, 17520 (2009).

[9] To make clear, in performing the audit, the Government used Respondent's perpetual inventory which documented each distribution it received from a supplier as well as each distribution it made to a customer.

Other Evidence

Mr. Ramsey personally stocks his listed chemical products in plexiglass display cases, which he has provided to his customers at his own expense to prevent theft. Tr. 338–40, 407–08. According to Mr. Ramsey, the cases prevent the public from having direct access to the product. *Id.* at 338. Mr. Ramsey further testified that he had provided the cases for more than ten years and had been doing so long before the 2006 enactment of the Combat Methamphetamine Epidemic Act (CMEA), which made placement of the product behind-the-counter a Federal requirement. *Id.* at 339. He also posted signs on the cases indicating the amount of a product that can be sold on a daily basis and testified that he was then in the process of sending his customers a letter explaining what they needed to do to comply with the CMEA's logbook requirement. *Id.* at 342.

Mr. Ramsey further testified that following Tennessee's enactment of the Tennessee Meth Free Act, which prohibited his customers from selling tablet-forms of ephedrine, he has not sold any tablet-form products and instead is selling only soft-gel products in blister packs. *Id.* at 352–53. Moreover, he accepted returned tablets and sent them, along with his remaining inventory, to a reverse distributor for destruction. *Id.* at 351–52. He also retained records of the destroyed products. *Id.; see also* RX 3, at 14–15.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) 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." *Id.* § 823(h). In making the public interest determination, Congress directed that the following factors be considered:

> (1) Maintenance by the [registrant] of effective controls against diversion of listed chemicals into other than legitimate channels;
>
> (2) Compliance by the [registrant] with applicable Federal, State, and local law;
>
> (3) Any prior conviction record of the [registrant] under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) Any past experience of the [registrant] in the manufacture and distribution of chemicals; and
>
> (5) Such other factors as are relevant to and consistent with the public health and safety.

Id.

"These factors are considered in the disjunctive." *Gregg & Son Distributors,* 74 FR 17517, 17520 (2009); *see also Joy's Ideas,* 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and I may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application for renewal of a registration. *Gregg & Son,* 74 FR at 17520; *Energy Outlet,* 64 FR 14269 (1999). Moreover, I am not required to make findings as to all of the factors. *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005).

The Government, however, bears the burden of proof. 21 CFR 1309.54. Having considered all of the factors, I conclude that the Government has failed to prove that Respondent's continued registration is inconsistent with the public interest. While I have also considered the ALJ's recommendation that I impose several compliance conditions on Respondent's registration, I conclude that the record does not support doing so. Accordingly, the Order to Show Cause will be dismissed.

As noted above, the Government's case was based primarily on Respondent's putative failure to maintain effective controls against diversion. More specifically, the Government alleged that: (1) Respondent had once lost a case of ephedrine, and that he failed to timely report the loss, (2) that Respondent was selling list I products in quantities which were "far in excess" of legitimate demand, and (3) that an audit found an overage of 732 bottles of one product. Show Cause Order at 2–3.

As explained in numerous cases, maintaining proper security for list I chemicals is a highly important consideration under factor one. Here, however, there is no dispute that Respondent maintains proper security of the products at its registered location. Rather, the Government relies on a single incident, which had occurred

nearly three years before the Show Cause Order was even filed, in which Respondent lost a case of product out the back of its truck.

It is undisputed that upon discovering the loss, Mr. Ramsey attempted to find the product. He reported the loss in writing to DEA within three days. *See* 21 U.S.C. 830(b)(1)(C). He also took corrective action to prevent a reoccurrence and there is no evidence that there has been one.

The Government nonetheless asserts that Respondent violated Federal law because it "failed to timely report" the loss "pursuant to 21 CFR 1310.05(a)(3) and (b)." Gov. Br. at 9. The Government does not explain, however, whether it relies on the provision of the regulation which requires that "whenever possible," an oral report shall be made "at the earliest practicable opportunity," or the provision which requires that a written report be filed "within 15 days after the regulated person becomes aware of the circumstances of the event." 21 CFR 1310.05(b); *see also* Gov. Br. 9.

What is clear is that Respondent's written report complied with the regulation. Moreover, it is not the role of those who perform quasi-judicial functions to make the Government's argument for it. Because the Government did not advance the argument that its allegation is based on Respondent's failure to give oral notification, I do not consider it. Accordingly, I reject the allegation that Respondent violated Federal law by failing to timely report the 2003 loss of listed chemicals.

I am also compelled to reject the allegation that Respondent was selling excessive quantities of listed chemicals. As noted above, because the Government Expert's methodology is unreliable, his findings as to both the monthly expected sales range and the statistical improbability of certain sales levels of ephedrine products in legitimate commerce at convenience stores are not supported by substantial evidence.[10] *Novelty Distributors,* 73 FR at 52693–94; *see also CBS Wholesale,* 74 FR at 36746.

Finally, the Government alleged that its audit of Respondent found an overage of 732 bottles of 36-count Rapid Action combination ephedrine tablets. Here again, the Government failed to meet its evidentiary burden. As noted above, the primary dispute over the audit involved the amount of Respondent's distributions to its customers. The Government did not, however, document how it arrived at its figure by showing what invoices (or transactions [11]) it included. Moreover, Respondent's evidence (which included the purchase invoices and the perpetual inventories Mr. Ramsey maintained) establishes that Mr. Ramsey's testimony accurately reflects the amount of the product he had distributed to the stores during the audit period. Finally, the Government failed to rebut this evidence. I thus reject the allegation as unsupported by substantial evidence.

While the ALJ found this allegation unproven, and further noted that Respondent's "perpetual inventory" records "exceeded the DEA's requirements to some extent," she nonetheless found that the logs submitted into evidence were "difficult to decipher, which makes a proper evaluation of their accuracy nearly impossible." ALJ at 29. The ALJ therefore recommended that as a condition of continuing his registration, I require that "Respondent shall improve and maintain its records of listed chemical product sales such that they are (a) clearly legible, (b) the product sold is clearly identified, and (c) the customer to whom products are sold is clearly identified such that all of its sales can be accounted for." [12] *Id.* at 43 (footnotes omitted).

Neither Federal law nor Agency regulations require that a list I chemical distributor maintain a perpetual inventory.[13] *See* 21 CFR 1310.03(a). And even assuming that the Agency has authority to impose conditions based on a registrant's maintenance of a record he has no obligation under the law to maintain, I conclude that the ALJ's conditions are unwarranted for several reasons.

First, the records are copies, and as such, do not necessarily establish that the originals are illegible. Second, the legibility of a person's handwriting is like beauty—it is in the eyes of the beholder. Having reviewed the records, I find that they are legible enough to understand. Third, the records were compiled from the invoices Respondent created for each store and transaction. In the event an entry was unreadable—and the Government does not maintain that any of the entries were—the original invoice could have been reviewed. Yet none of Respondent's sales invoices are in the record, and thus, it is not possible to assess whether they were being properly maintained and were legible.[14] Accordingly, there is no basis to support the ALJ's conclusion that Respondent's records "render an accurate assessment of its accountability extremely difficult." ALJ at 42. The evidence therefore supports neither "admonish[ing] the Respondent to improve its recordkeeping," nor the imposition of the ALJ's proposed condition. *Id.*

The ALJ also recommended that I impose the condition that "Respondent is only authorized to handle soft gel listed chemical products." *Id.* at 43. As I have previously explained, conditions on a registration "must be related to what the Government has alleged [15] and proved in any case." *Janet L. Thornton,* 73 FR 50354, 50356 (2008). In her decision, the ALJ noted that there is "no evidence that the Respondent has violated the [Tennessee] Meth Act," and that "the record demonstrates that the Respondent is effectively adhering to the [Tennessee] Meth Act and has limited the sales to its customers strictly to gel-form ephedrine." ALJ at 41. Likewise, there is no evidence that Respondent had violated the then newly enacted Combat Methamphetamine Epidemic Act.

This being so, there is no basis for imposing this condition. The purpose of conditions is not simply to replicate what is already required by State or Federal law. *Cf. Joseph Gaudio,* 74 FR 10083, 10095 (2009) (rejecting ALJ's recommendation to continue a registration on the condition that a registrant refrain from illegal activity, noting that there were numerous State and Federal laws which already prohibited the activity). Rather, the purpose is to remedy identified and proven deficiencies in a registrant's policies and practices where those deficiencies are not so serious or

[10] While the Government has the burden of proof, it also failed to produce any analysis of Respondent's sales data to show what its average monthly sale was. *See also* Resp. Br. 22 (arguing that the Government "presented no evidence that [the Expert] review any information concerning [its] business practices or its List I sales"). Accordingly, even if its Expert's methodology had not been subsequently shown to be invalid, I would still be compelled to reject the allegation.

[11] The Government did not use Respondent's sales invoices, but rather, the perpetual inventories it maintained for each lot of product it obtained from a distributor.

[12] The ALJ suggested that Respondent could improve the legibility of his records by either "typing or *carefully* handwriting the logs." ALJ at 43 n.15.

[13] Nor is there a requirement that a registrant who handles controlled substances maintain a perpetual inventory. *See* 21 CFR 1304.21(a).

[14] In light of the fact that Combat Methamphetamine Epidemic Act eliminated the thresholds for combination ephedrine products such that all "transactions, regardless of size, are subject to recordkeeping and reporting requirements as set forth in" 21 CFR 1310, 21 CFR 1310.04(g), Respondent should ensure that its recordkeeping complies with the regulations.

[15] To make clear, conditions can be imposed based on any allegation which the Government provides adequate notice of in accordance with the Due Process Clause and Administrative Procedure Act (and DEA regulations) and which it proves at a hearing.

extensive as to warrant revocation of a registration but which nonetheless threaten the public interest. Because there is no evidence that Respondent has sold forms of list I products in violation of either State or Federal law, there is no basis to impose the condition.[16]

In conclusion, the Government has not established that Respondent has committed any acts which either render its registration inconsistent with the public interest or which would support the imposition of conditions on its registration. Accordingly, the Order to Show Cause will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) and 824(a), as well as 28 CFR 0.100(b) and 0.104, I order that the application of M & N Distributors for renewal of its DEA Certificate of Registration be, and it hereby is, granted. I further order that the Order to Show Cause issued to M & N Distributors be, and it hereby is, dismissed. This order is effective immediately.

Dated: May 6, 2010.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Christopher Henry Lister, P.A.; Revocation of Registration

On November 3, 2009, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Christopher Henry Lister, P.A. (Respondent), of Hesperia, California. The Order proposed the revocation of Respondent's DEA Certificate of Registration, ML0817900, as a practitioner, and the denial of any pending applications to renew or modify his registration, on the ground that he had committed acts which render his registration inconsistent with the public interest. Show Cause Order at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Show Cause Order alleged that Respondent violated Federal law by issuing controlled substance prescriptions "outside [of] the usual course of professional practice," which lacked a "legitimate medical purpose, and that he violated California law because he issued the prescriptions "without an appropriate prior examination and a medical indication." *Id.* at 1–2 (citing 21 CFR 1306.04(a) & Cal. Bus. & Prof. Code § 2242(a)). More specifically, the Order alleged that on June 16, 2009, an undercover agent purchased through an intermediary a prescription for 60 tablets of OxyContin 80 mg., and that Respondent "never met or * * * much less conducted a physical examination" of, the person for whom he wrote the prescription. *Id.* at 2.

Next, the Show Cause Order alleged that on June 25, 2009, an undercover agent purchased though an intermediary prescriptions for 90 tablets of OxyContin 80 mg., which were written in the names of four different persons, and that Respondent had never met or conducted a physical examination of any of these persons. *Id.* Finally, the Show Cause Order alleged that on October 8, 2009, an informant purchased from Respondent prescriptions for OxyContin 80 mg., Xanax 2 mg., Valium 10 mg., and Lortab 10/500 mg., which were post–dated for October 29, 2009, and written in the names of three different persons he never physically examined. *Id.*

Based on the above, I further concluded that Respondent's continued registration during the pendency of the proceeding would "constitute[] an imminent danger to the public health and safety." *Id.* Therefore, pursuant to my authority under 21 U.S.C. 824(d), I immediately suspended Respondent's registration. *Id.* The Order further explained that Respondent had the right to request a hearing on the allegations, the procedure for doing so, and that if he failed to do so, the scheduled hearing would be cancelled and he would be deemed to have waived his right to a hearing. *Id.*

On November 5, 2009, a DEA Special Agent personally served Respondent with the Order to Show Cause and Immediate Suspension of Registration. Moreover, on November 6, 2009, Government Counsel served a copy of the Order on Respondent by First-Class Mail to him at his registered location.

More than thirty days have now passed since the service of the Order to Show Cause and Immediate Suspension, and neither Respondent, nor anyone purporting to represent him, has requested a hearing. I therefore find that Respondent has waived his right to a hearing, 21 CFR 1301.43(d), and issue this Decision and Final Order without a hearing based on the record submitted by the Government. I make the following findings.

Findings

Respondent is the holder of DEA Certificate Registration, ML0817900. Respondent last renewed his registration on April 2, 2008; the registration does not expire until March 31, 2011.

Respondent also holds a Physician Assistant (PA) License issued by the Physician Assistant Committee of the Medical Board of California. On November 6, 2009, the Executive Officer of the Physician Assistant Committee filed a petition for an interim order of suspension of Respondent's state license. On November 12, 2009, a state Administrative Law Judge (ALJ) granted the petition and immediately suspended Respondent's PA license. The ALJ also ordered that Respondent appear for hearing on November 30, 2009, to show cause why the interim order suspending his license "should not remain in full force and effect pending the issuance of a final decision by the Medical Board of California." Interim Order of Suspension at 2, *Portman* v. *Lister* (Cal. Office. of Admin. Hearings, No. 1E–2008–195465).

On November 30, 2009, a hearing was held before another state ALJ. Following the hearing, the ALJ found that:

> [o]n October 8, 2009, a Bureau of Narcotics Enforcement confidential informant (CI) met with respondent at the CI's residence. The meeting was monitored by a DEA agent. During the meeting the CI provided respondent with a list of names and asked respondent to prescribe OxyContin, Xanax, Ambien, and Valium to the listed individuals in exchange for $750 in cash. Respondent did as requested, and took the $750 cash payment.

Order of Interim Suspension at 2, *In re Lister.*

Based on this finding, the ALJ concluded "that respondent has engaged in acts constituting violations of the Medical Practice Act" and that the State had "show[n] that permitting [him] to continue to engage in the profession for which [his] license was issued will endanger the public health, safety, or welfare." *Id.* at 3 (citing Cal. Gov. Code § 11529(a)). In a footnote, the ALJ further explained that "[b]y prescribing dangerous drugs and controlled substances to the CI without an appropriate medical examination and without any medical indication * * * Respondent violated [various] provisions of the Medical Practice[] Act" including, *inter alia,* Cal. Bus. & Prof. Code § 2242(a) ("furnishing dangerous drugs without examination"), and Cal. Health & Safety Code § 11153(a) ("prescribing controlled substances without a legitimate medical purpose"). *Id.* at n.6. The ALJ thus granted the

[16] For the same reason, there is no basis to impose the ALJ's third condition.