

Respondent did not then contact R & S to independently verify whether Ogele had provided her with all of the invoices. See Tr. 347. Those invoices would have shown that Ogele had ordered large amounts of additional controlled substances such as promethazine cough syrup with codeine and various benzodiazepines that were unrelated to "the Nigeria project." Gov. Ex. 12 at 8, 13, 15, & 20. Nor did she exercise her right as a director of ISMP to inspect its books, records, and documents. See Cal. Corp. Code section 6334 (West 2006) ("Every director shall have the absolute right at any reasonable time to inspect and copy all books, records and documents of every kind * * * of the corporation of which such person is a director.").

By the date the Show Cause Order was served on her, Ogele had obtained other drugs from R & S and had also placed numerous orders with Priority Healthcare. See Gov. Ex. 11. Taking timely action such as obtaining the invoices from R & S would have uncovered the fact that Ogele was ordering additional controlled substances and engaged in diversion. Furthermore, exercising her right as a director to inspect all of ISMP's records including its accounts payable and checking account records would likely have shown that Ogele was ordering from an additional supplier.

To be sure, Ogele may have attempted to obstruct any such inquiry by withholding documents that showed that he was ordering controlled substances from Priority Healthcare. Respondent did not, however, take anything bordering on timely action to investigate the extent of Ogele's illegal use of her registration. Her failure to take even the most rudimentary steps to investigate the misuse of her registration was a breach of her duty as a registrant. Moreover, it likely allowed Ogele to continue his criminal activity well past the point at which it should have been stopped.

Consistent with a registrant's obligation to "provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a), every registrant has a duty to conduct a reasonable investigation upon receiving credible information to suspect that a theft or diversion has occurred. Performing a reasonable investigation is essential to preventing the continuation of criminal activity. While the precise scope of this duty necessarily depends upon the facts and circumstances, doing nothing for months—as Respondent did here—clearly warrants a finding that a

registrant has committed acts which threaten public health and safety.

In her analysis of factor five, the ALJ further observed that Respondent "exhibited no remorse for her conduct at the hearing" and "downplayed her misconduct." *Id.* at 36–37. I agree. Beyond that, I am especially disturbed by Respondent's testimony under oath that she did not know that Ogele was ordering controlled substances until DEA investigators informed her of this during the January 15, 2004 meeting. As explained above, this testimony was fundamentally inconsistent with the letter Respondent submitted in response to the Show Cause Order in which she stated that she had authorized the ordering of 300 bottles of hydrocodone and vicodin between May 2003 and August 2003. See, e.g., ALJ Ex. 2, at 2. Of course, Respondent's written statement was submitted before Ogele was arrested and pled guilty to drug offenses. I thus conclude that Respondent lied under oath to downplay her responsibility for supplying Ogele with the means to obtain his wares. Such conduct buttresses the conclusion that Respondent cannot be entrusted with a registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as 28 CFR 0.100(b) & 0.104, the order of immediate suspension of DEA Certificate of Registration, AL8962993, issued to Rose Mary Jacinta Lewis, M.D., is hereby affirmed. The Office of Diversion Control is further directed to cancel Respondent's DEA number. This order is effective February 28, 2007.

Dated: January 19, 2007.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Wild West Wholesale Revocation of Registration

On August 18, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Wild West Wholesale (Respondent) of Cedaredge, Co. The Show Cause Order proposed to revoke Respondent's DEA Certificate of Registration, 005516WWY, as a distributor of list I chemicals, and to deny any pending applications for

renewal or modification of the registration, on the ground that Respondent's continued registration is inconsistent with the public interest. Show Cause Order at 1.

The Show Cause Order specifically alleged that Respondent distributed list I chemical products containing ephedrine, a precursor chemical used to manufacture methamphetamine, a Schedule II controlled substance. See *id.* at 1–2. The Show Cause Order alleged that Respondent distributed combination ephedrine products to gas stations and convenience stores, which are non-traditional retailers of these products. *Id.* at 2. The Show Cause Order further alleged that Respondent was distributing "approximately five or more case of various ephedrine products to its 45 customers each month," *id.*, and that only a very small percentage of the licit retail market for these products is sold in convenience stores and gas stations. *Id.* 2–3. Finally, the Show Cause Order alleged that Colorado and adjacent states "have experienced a proliferation of small methamphetamine laboratories" and that "[l]aw enforcement officials have observed that a substantial proportion of precursors found at illicit methamphetamine sites have involved non-traditional brands sold through convenience stores." *Id.*

On September 26, 2005, the Show Cause Order was served on Respondent by first class mail.¹ On October 14, 2005, Respondent, through its counsel, requested a hearing. The case was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who ordered the parties to prepare pre-hearing statements. However, on February 22, 2006, Respondent withdrew its request for a hearing. The ALJ then ordered that the proceeding be terminated so that the investigative file could be forwarded to me for final agency action.

I find that Respondent has waived its right to a hearing. I therefore enter this final order without a hearing based on information contained in the investigative file.

Findings

Respondent is a supplier of sundry items to approximately forty-five convenience stores and gas stations in western Colorado. Among the items

¹ The Show Cause Order was initially sent by certified mail to the street address of Respondent's registered location but was returned with a notation indicating that Respondent's owner had moved and that the time for forwarding mail had lapsed. This address was also used by Respondent's owner when she submitted a renewal application in April 2005. In May 2004, Respondent's owner had submitted a request for a change of its registered location to the address at which Respondent was eventually served.

which Respondent distributes are products containing the list I chemicals pseudoephedrine and ephedrine. Respondent is owned by Ms. Brenda Garcia and operated out of her home in Cedaredge, Co.

While ephedrine and pseudoephedrine have therapeutic uses, they are easily extracted from lawful over-the-counter products and are used in the illicit manufacture of methamphetamine, a schedule II controlled substance. *See* 21 U.S.C. 802(34). Methamphetamine is a powerful and addictive central nervous system stimulant. *See Gregg Brothers Wholesale Co.*, 71 FR 59830 (2006). The illegal manufacture and abuse of methamphetamine pose a grave threat to this county. Methamphetamine abuse has destroyed numerous lives and families and ravaged communities. Moreover, because of the toxic nature of the chemicals used to make methamphetamine, its manufacture causes serious environment harms. *Id.*

Respondent holds Certificate of Registration, #005516WWY, which authorizes it to distribute pseudoephedrine and ephedrine at the registered location of 224 SW 13th Circle, Cedaredge, Co. Respondent's registration expired on May 31, 2005, and was subsequently retired on December 31, 2005. Respondent did, however, file a renewal application on April 28, 2005, which was received by DEA on May 5, 2005.

On May 12, 2004, Respondent's owner requested a modification of Wild West's registration seeking to change its registered location from the SW 13th Circle address to her home. Thereafter, on May 24, 2004, Respondent's owner submitted additional information. Included in this information was a sales report from one of Respondent's suppliers, Proactive Labs, Inc., which documented the firm's purchase of combination ephedrine products on various dates between December 12, 2002, and March 3, 2004. These records showed that during this period, Respondent purchased from Proactive Labs a total of 426,912 dosage units of combination ephedrine products. As noted in previous decisions, DEA has issued numerous warning letters to Proactive Labs because its products have been found repeatedly at illegal methamphetamine labs. *See D & S Sales*, 71 FR 37607, 37608 (2006).

Thereafter, on July 14, 2004, two Diversion Investigators (DIs) went to Respondent's new location to interview its owner and conduct a security inspection. During the interview, Respondent's owner told the DIs that list I chemicals comprised five to ten

percent of its sales. She also informed them that Respondent obtained list I products from two additional suppliers. Respondent further provided the DIs with a customer list.

Several months later, one of the DIs contacted twelve of Respondent's customers. Most of the customers claimed either that they did not purchase, or purchased only small amounts of, list I products from Respondent.

On July 13, 2005, the DIs conducted an additional interview of Respondent's owner. During the interview, Respondent's owner told the DIs that Proactive Labs had been her exclusive supplier of ephedrine products since February 2005. Respondent's owner further told the DIs that the company had notified her that effective July 1, 2005, it was selling its products lines to Advantage Healthcare.

Respondent's owner informed the DIs that prior to July 1, 2005, when Colorado law changed to require that pseudoephedrine and ephedrine products be sold in blister packaging, she had sold 48-count bottles of Bronch-eze Asthma Relief, a combination ephedrine product. Respondent's owner stated that she paid \$1.26 per bottle and that the bottles sold at retail for \$5.99. Respondent's owner told the DIs that a 48-count blister package cost \$1.49 per box and sold at retail for \$6.99. She also informed the DIs that the six-count combination ephedrine blister packs cost \$.25 each and sold at retail for \$.99.

Respondent's owner provided the DIs with twelve invoices documenting its purchases of combination ephedrine products from Proactive Labs/ Advantage Healthcare between January 31, 2005, and July 19, 2005. The invoices showed that Respondent had purchased \$7003.80 worth of 48-count bottles and \$2837.53 worth of six-count packets between January 31, 2005, and June 9, 2005. The two invoices for July 2005 showed that Respondent had purchased \$1712.96 worth of 48-count blister pack boxes. Relatedly, at the time of the inspection, Respondent had on hand 543 bottles (48-count), which were to be returned following the change in Colorado law.

Based on the retail price information provided to the DIs, Respondent distributed combination ephedrine products with a retail sales value of \$40,916.76,² over the approximately six-month period or \$6819.46 per month. On a per store basis, the estimated

average monthly retail sale of the products was \$151.54.

In numerous cases, DEA has established through expert testimony the monthly expected sales of combination ephedrine products by non-traditional retailers such as convenience stores and gas stations to meet legitimate demand, i.e., the purchase of the products for their medically approved use as a bronchodilator to treat asthma. *See, e.g., T. Young Associates, Inc.*, 71 FR 60567, 60567 n.2 & 60568 (2006); *Tri-County Bait Distributors*, 71 FR 52160, 52161–62 (2006); *D & S Sales*, 71 FR 37607, 37608–09 (2006). In these cases, DEA has proved by substantial evidence that the monthly expected retail sales range for combination ephedrine products by non-traditional retailers is between \$0 and \$25, with an average of \$12.58. *See T. Young*, 71 FR at 60568; *Tri-County Bait*, 71 FR at 52162; *D & S*, 71 FR at 37609. DEA has also established that a monthly retail sale of \$60 of ephedrine products “would occur about once in a million times in random sampling.” *T. Young*, 71 FR at 60568 (int. quotations and citations omitted).

Respondent's owner also provided the DIs with a customer list. Using the customer list, a DI visited twenty-one of the stores and interviewed their managers regarding whether they sold list I products and, if so, the volume sold. At fifteen of the stores, the managers estimated that they were selling \$60 or more per month of combination ephedrine products. Indeed, at ten of the stores, the managers estimated that they were selling \$100 or more per month of the products, and at eight of the stores, the managers estimated that they were selling \$300 or more per month.

Discussion

As an initial matter, the scope of this proceeding must be determined. According to the investigative file, Respondent's registration expired on May 31, 2005. On April 28, 2005, however, Respondent's owner submitted a renewal application. DEA received the application on May 5, 2005, and charged the application fee to its owner's credit card.

Under the Administrative Procedure Act (APA), “[w]hen [a] licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency.” 5 U.S.C. 558(c). DEA's regulation which addresses renewal applications merely

² This figure was calculated based on the invoice amounts minus the inventory that was being returned.

states that “[a]ny person who is registered may apply to be reregistered not more than 60 days before the expiration date of [her] registration.” 21 CFR 1309.31(b). This regulation does not specify a date by which DEA must receive a renewal application in order for an existing registration to be continued in accordance with the APA.

Another DEA regulation addresses the renewal of an existing registration when Show Cause Proceedings are pending. See 21 CFR 1309.45 (“Extension of registration pending final order”). This regulation provides that:

[i]n the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator issues his order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

Id.

As demonstrated by its text, this regulation clearly contemplates that a Show Cause proceeding must be ongoing in order to trigger the requirement that a registrant submit a renewal at least 45 days in advance of the registration's expiration date in order to continue the registration. Here, however, Respondent's renewal was submitted four months before the Show Cause Order was issued and thus this regulation is not applicable. Instead, the timeliness of Respondent's renewal application is governed by 1309.31, which imposes no deadline by which the application must be filed. Therefore, I conclude that Respondent submitted a timely renewal application, and that under the APA, her registration has remained in effect pending the final order in this proceeding.

The Public Interest Analysis

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. section 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). In this case, I conclude that Factors Four and Five establish that Respondent's continued registration would be “inconsistent with the public interest,” 21 U.S.C. 823(h), and that Respondent's registration should be revoked and its pending application for renewal should be denied.

Factors Four and Five—The Registrant's Past Experience in the Distribution of Chemicals and Other Factors Relevant to and Consistent With Public Health and Safety

As found above, the illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation. Cutting off the supply source of methamphetamine traffickers is of critical importance in protecting the public from the devastation wreaked by this drug.

While combination ephedrine products have a legitimate medical use as a bronchodilator to treat asthma, DEA orders have established that convenience stores and gas stations constitute the non-traditional retail market for legitimate consumers of products containing ephedrine. See, e.g., *Tri-County Bait Distributors*, 71 FR at 52161; *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, substantial and compelling”); *Jay Enterprises*, 70 FR 24620, 24621 (2005) (noting “heightened risk of diversion” should application be granted).

DEA orders thus establish that the sale of certain list I chemical products by non-traditional retailers is an area of particular concern in preventing diversion of these products into the illicit manufacture of methamphetamine. See, e.g., *Joey Enterprises*, 70 FR 76866, 76867 (2005). As *Joey Enterprises* explains, “[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.” *Id.* 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”); *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”).

Here, nearly all of Respondent's customers are convenience stores and gas stations, which are non-traditional retailers of list I chemical products. Most significantly, the investigative file establishes that the combination ephedrine products distributed by Respondent were not being sold to meet legitimate consumer demand but rather were being diverted to supply the illicit manufacturers of methamphetamine. As found above, the average monthly retail sales value of the combination ephedrine products distributed by Respondent was \$151.54 per store. This

figure grossly exceeds the monthly expected sales range of \$0 to \$25 (with an average of \$12.58) by convenience stores to meet legitimate demand for these products as an asthma treatment. See *T. Young*, 71 FR at 60568; *D & S Sales*, 71 FR at 37609.

Indeed, a monthly retail sale of \$60 of ephedrine products at a convenience store should “occur about once in a million times in random sampling.” *T. Young*, 71 FR at 60568. The \$151.54 average retail sale value of Respondent’s products is 2.5 times this amount. Moreover, this figure is an average for all forty-five stores serviced by Respondent over a seven-month period. It is thus even more improbable than a one in a million probability that Respondent’s products were being purchased to meet legitimate demand.

I therefore conclude that a substantial portion of Respondent’s products were diverted into the illicit manufacture of methamphetamine. See *T. Young*, 71 FR at 60572; *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”).³ Moreover, “the diversion of list I chemicals into the illicit manufacture of methamphetamine poses the same threat to public health and safety whether a registrant sells the products knowing they will be diverted, sells them with a reckless disregard for the diversion, or sells them being totally unaware that the products were being diverted.” *T. Young*, 71 FR at 60572 (citing *D & S Sales*, 71 FR at 37610–12, & *Joy’s Ideas*, 70 FR at 33198). In short, the statutory text does not require that the Government prove that a registrant acted with any particular *mens rea* to sustain a public interest revocation. *T. Young*, 71 FR at 60572. Accordingly, adverse findings are warranted under these factors even if Respondent’s owner was unaware that its products were being diverted.

Here, while Respondent (and its owner lacks a criminal record) and the file does not establish that Respondent has failed to comply with applicable laws or lacks effective controls,⁴ I

nonetheless conclude that Factors Four and Five compel the conclusion that Respondent’s continued registration would be inconsistent with the public interest.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h) & section 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, 005516WWY, issued to Wild West Wholesale be, and it hereby is, revoked. I further order that Wild West Wholesale’s pending applications for modification and/or renewal of its registration be, and they hereby are, denied. This order is effective February 28, 2007.

Dated: January 20, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–1316 Filed 1–26–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0022]

Electronic Surveillance Technology Section; Agency Information Collection Activities: Current Collection; Comment Requested

ACTION: 30-Day Notice of Information Collection Under Review of a Currently Approved Collection for which to due to Expire; Cost Recovery Regulations, Communications Assistance for Law Enforcement Act of 1994.

The Department of Justice (DOJ), Federal Bureau of Investigation (FBI) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 71, Number 229, pages 69146–69147 on November 29, 2006, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional “thirty days” for public comment until February 28, 2007. This process is conducted in accordance with 5 CFR 1320.10.

contains no evidence to support a finding that Respondent does not maintain effective controls because it was aware of diversion occurring at the retail level and failed to act.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Porter Dunn, Federal Bureau of Investigation, U.S. Department of Justice, ESTS, 14800 Conference Center Drive, Suite 200, Chantilly, Virginia 20151.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information

(1) *Type of Information Collection:* Approval, without change, of a currently approved collection for which approval is due to expire.

(2) *Title of the Form/Collection:* Cost Recovery Regulations, 28 CFR 100.9 et seq.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. Federal Bureau of Investigation, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. The Cost Recovery Regulations have been adopted to assist the telecommunications industry in any submission of claims pursuant to Section 109(a) and (e) of the Communications Assistance for Law Enforcement Act, codified at 47 U.S.C. 1001–1010 (1994).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* The average time burden of the approximately 4 respondents to provide the information requested is approximately 4 hours per response and an estimated 5 responses (per respondent).

³ This finding is also supported by the customer verifications. At nearly half of the twenty-one stores visited, the managers told the DIs they were selling quantities of combination ephedrine products that would sell for \$100 or more per month; at eight of the stores, the managers estimated that they were selling quantities of \$300 or more per month.

⁴ The Government bears the burden of proof on each factor even when a registrant waives its right to a hearing. In this case, the investigative file