

records of this Agency,¹ I find that Respondent's registration expired on October 31, 2008, and that Respondent has not submitted a renewal application, let alone a timely one (which would have kept his registration in effect pending the issuance of this decision).

It is well settled that "[i]f a registrant has not submitted a timely renewal application prior to the expiration date, then the registration expires and there is nothing to revoke." Ronald J. Riegel, 63 FR 67132, 67133 (1998); see also *William W. Nucklos*, 73 FR 34330 (2008). Because Respondent's registration has expired and there is no pending application to act upon, I conclude that this case is now moot.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) and 0.104, I hereby order that the Order to Show Cause issued to Sylvester A. Nathan, M.D., be, and it hereby is, dismissed.

Dated: April 3, 2009.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05-43]

Gregg & Son Distributors; Grant of Conditional Registration

On August 3, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Gregg & Son Distributors (Respondent), of Powell, Tennessee. The Show Cause Order proposed the revocation of, and the denial of its pending application to renew, Respondent's DEA Certificate of Registration, which authorizes it to distribute the List I chemicals pseudoephedrine and ephedrine, on the ground that its registration "is

inconsistent with the public interest." Order to Show Cause at 1.

More specifically, the Show Cause Order alleged that Respondent's customers for List I chemical products "are almost exclusively * * * entities such as convenience stores and small independent grocery stores," and that these retailers are a primary source for the diversion of these products into the illicit manufacture of methamphetamine, a schedule II controlled substance. *Id.* at 1-2. The Order further alleged that Respondent was selling "products that are not sold in traditional retail outlets, including over one dozen ephedrine products and various pseudoephedrine products," *id.* at 2-3, that according to an expert utilized by the Agency, "the average small store could expect to sell monthly only about \$ 10.00 to \$ 30.00 worth of pseudoephedrine products," and "that the potential for sales of combination ephedrine products [was] about only one-fourth of [these] sales levels." *Id.* at 4. Relatedly, the Order alleged that "it is highly unlikely that [Respondent's customers] would sell a large volume of List I chemical products for legitimate uses," that Respondent's "sales of combination ephedrine products and pseudoephedrine products are inconsistent with the known legitimate market and known end-user demand for products of this type," and that Respondent "is serving an illegitimate market for these products." *Id.* at 4-5.

The Show Cause Order further alleged that in March 2005, DEA Investigators conducted an inspection of Respondent. *Id.* at 2. According to the allegations, the Investigators conducted an audit of six ephedrine products distributed by Respondent between December 27, 2003, and March 15, 2005, and found "substantial underages and overages for these products." *Id.* at 3.

The Order also alleged that during the inspection, the Investigators discovered that Respondent sold "'lovers' roses,' devices with small roses contained inside a glass vial cylinder," and that "[t]hese products are considered drug paraphernalia because the vials are used to smoke methamphetamine and [crack] cocaine." *Id.* The Order further alleged that Mr. Dennis Gregg, Respondent's owner, "acknowledged that he was aware of the illicit use of lovers' roses." *Id.*

Finally, the Order alleged that after the inspection, Investigators visited three of Respondent's customers and obtained information which indicated that Respondent's products were being diverted. *Id.* at 3. More specifically, the Order alleged that at the first store, one customer purchased two (forty-eight

count) bottles each day, and that at a second store, the manager stated that she had only a few customers who purchased the products but that they did so regularly, and "that she believed that most of the List I chemical products sold in her store went to 'meth labs.'" *Id.* at 3. Finally, the Order alleged that at the third store, the owner stated "that he was a former law enforcement officer" and that "he was certain that most or all of the ephedrine sold at his store [was] used for illicit methamphetamine production." *Id.* at 3-4.

On or about August 30, 2005, Respondent requested a hearing on the allegations; the matter was placed on the docket of the Agency's Administrative Law Judges (ALJ). On April 18 and 19, 2006, a hearing was held in Nashville, Tennessee, at which both parties called witnesses to testify and submitted documentary evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact, legal conclusions, and argument.

On February 29, 2008, nearly twenty-two months after the hearing, the ALJ issued her recommended decision (ALJ). Because Respondent's sales levels of ephedrine products "far exceed the expected legitimate market demand," the ALJ concluded that the Government had established its *prima facie* case that its continued registration is inconsistent with the public interest. ALJ at 41. The ALJ reasoned, however, that a sanction less severe than revocation was warranted because Tennessee had recently enacted legislation that "placed extensive limits upon the products [Respondent could] sell," that Respondent was in "compliance with the Act," *id.*, and that the Agency had not provided evidence that its sales of gel cap products were excessive. *Id.* at 39. The ALJ further concluded that there was a "lack of evidence in [the] record showing that soft-gel listed chemical products have actually been made into methamphetamine at illicit laboratories." *Id.* at 41.

The Government filed exceptions to the ALJ's decision, and Respondent filed a Response to the Government's exceptions.¹ Thereafter, the record was forwarded to me for final agency action.

¹ Therein, the Government argued that the record not only showed that listed chemical products in gel cap form have been diverted, but that in various decisions I have previously rejected the ALJ's reasoning that the Agency cannot revoke a registration until the actual diversion of gel cap products is substantiated. Exceptions at 2-3 (citing *Holloway Distributing*, 72 FR 42118 (2007), *T. Young Associates*, 71 FR 60567 (2006)).

¹ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding-even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request, to an opportunity to show to the contrary." 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). Respondent can dispute these facts by filing a properly supported motion for reconsideration within fifteen days of service of this order, which shall begin on the date this order is mailed.

Having considered the entire record in this matter, I conclude that the Government has not established a *prima facie* case that Respondent's continued registration is inconsistent with the public interest. I conclude, however, that Respondent violated federal law by distributing drug paraphernalia. While this conduct warrants the suspension of Respondent's registration, because it has otherwise complied with federal law and regulations I conclude that the suspension should be stayed. I make the following findings.

Findings of Fact

Respondent is a distributor of sundry items including non-prescription drug products containing ephedrine and pseudoephedrine to convenience stores, small groceries, and gas stations located in eastern Tennessee.² Tr. 169.

Respondent is owned by Mr. Dennis Gregg and is run out of Mr. Gregg's home in Powell, Tennessee. *Id.* at 168–69; GX 1. Mr. Gregg has been involved in the wholesale distribution business since 1973 and started Respondent sometime around 1991.³ *Id.* at 171.

Respondent has held a DEA Certificate of Registration to distribute ephedrine, pseudoephedrine and phenylpropranolamine (PPA)⁴ since 1998. GX 1, at 2. While the expiration date of the last registration issued to

Respondent is September 30, 2005, *id.*, on August 8, 2005, Respondent filed an application to renew its registration. Joint Status Report at 1. I therefore find that Respondent filed a timely renewal application and that its registration remains in effect pending the issuance of this Order. *See* 5 U.S.C. § 558(c).

Both ephedrine and pseudoephedrine have legitimate therapeutic uses.⁵ *See, e.g., Tri-County Bait Distributors*, 71 FR 52160, 52161 (2006). Both chemicals are, however, regulated as list I chemicals under the Controlled Substances Act because are they extractable from non-prescription drug products and have been frequently diverted into 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). As noted in numerous Agency decisions, the illegal manufacture and abuse of methamphetamine pose a grave threat to this Nation. *Id.* Methamphetamine abuse has destroyed numerous lives and families, and has had a devastating impact on many communities. *Id.* Moreover, because of the toxic nature of the chemicals used in making the drug, illicit methamphetamine laboratories create serious environmental harms. *Id.*

The Investigation of Respondent

Respondent was first inspected by a DEA Investigator in 1998. Tr. 239. At the time of the inspection, Respondent was selling bottled pseudoephedrine, and during the inspection, the Investigator told Mr. Gregg that "pseudoephedrine was a very dangerous product." *Id.* at 179. The DI, however, made no similar reference to ephedrine being dangerous. *Id.* at 241. Thereafter, Respondent stopped selling bottled pseudoephedrine and limited his sales of the product to two-tablet packages. *Id.* at 179–80. Respondent did, however, continue to sell combination ephedrine products in bottles containing forty-eight and sixty tablets, as well as six-tablet packages. *Id.* at 180.

In August 2003, another DI requested that Respondent provide him with information regarding its average monthly sales of List I products to its various customers. *Id.* at 182–83. Mr. Gregg's wife compiled the information and provided it to the DI. *Id.* at 183–84; *see also* RX 6. The DI subsequently

called Mr. Gregg's wife and told her that the report was "exactly what he needed." Tr. 183. The DI did not raise any objection as to the quantities of products being sold by Respondent. *Id.*

On March 15, 2005, several DIs visited Respondent to perform an inspection. As part of the inspection, the DIs obtained a product list (GX 3) from Mr. Gregg and chose several products to be audited. Tr. 58–61. While the DIs obtained various records from Respondent and commenced an audit, *id.*, the Government did not introduce into evidence the results of the audit.⁶

During the audit, and upon determining that Respondent was distributing what he termed "gray market products," one of the DIs asked Respondent to voluntarily surrender his registration. *Id.* at 33. During the hearing, the DI testified that he did so even though there was no evidence that Respondent had violated any rule of the Agency and that he had requested the surrender "solely based on [Respondent's] handling * * * of gray market products." *Id.* at 51.

The DI further testified that during the inspection, he determined that Respondent was selling an item known as a "Love Rose."⁷ *Id.* at 33. According to the DI, this item, which includes a small flower packaged inside of a glass tube, constitutes "drug paraphernalia" because it is easily adapted for use in, and frequently used for, smoking both crack cocaine and methamphetamine, and is "commonly referred to as [a] crack pipe." *Id.* at 33–34.

During the inspection, Mr. Gregg acknowledged that he knew that this item was used to smoke crack and told the DI "that he didn't want to sell them anymore." *Id.* at 35. Mr. Gregg testified that approximately a month before the inspection he had decided that because the item was misused, once he sold his remaining stock of the item (which he did to a single person, *id.* at 293), he would stop carrying them. *Id.* at 218–19. According to Mr. Gregg, several of his customers had told him that they thought the product was "being used for a crack pipe," but that he would "occasionally" see people in stores buying this item and that with respect to some of them he "could tell they're not going to smoke something with it."

⁶ Mr. Gregg maintained that the audit was inaccurate because the DIs had left out numerous invoices documenting both Respondent's purchases and its distributions. *See* RX 5. Because the Government did not introduce the audit results, it is unnecessary to resolve this factual dispute.

⁷ Throughout the proceeding, the parties referred to this item as both a "Love Rose" and "Lover's Rose." Accordingly, these terms are used interchangeably in this decision.

The Government further argued that the ALJ ignored its evidence of Respondent's sales of gel cap products between June 2005 and November 2005, which showed it was "sell[ing] inordinate amounts of ephedrine-based products in gel cap form." *Id.* at 5. In support of its contention, the Government provided in its exceptions a list of Respondent's average monthly sales of these products to its various customers during this period. *Id.* at 6–9. Noting testimony in another proceeding that the average monthly retail sale of ephedrine products at convenience stores was \$12.48, and that a monthly retail sale of \$60.00 "at a convenience store would occur about once in a million times in random sampling," *id.* at 9, the Government contended "that virtually all" of Respondent's gel-cap ephedrine customers were "selling extraordinary amounts [which are] far beyond what would be expected in a legitimate market." *Id.*

While I consider the calculations, I note that this data was not provided—as it should have been—while the record was open. To make clear, it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding. *Cf. Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36503 n.25 (2007).

² Respondent also has customers in North Carolina and Virginia. Tr. 169.

³ The record does not establish whether Respondent is organized as a corporation, a partnership, or a sole proprietorship.

⁴ While Respondent has held a registration to distribute PPA since 1998, it is undisputed that Respondent had long since stopped selling products containing PPA and had requested that it be deleted from the list of chemicals it is authorized to distribute. Tr. 178.

⁵ Under the Food, Drug and Cosmetic Act, ephedrine (in combination with guaifenesin) is currently approved for marketing as a non-prescription bronchodilator. *See* 70 FR 40233 (2005).

Id. at 292. As for other customers he saw purchasing the items, Mr. Gregg maintained that he could not “judge them” and what they would use the product for because he is “just a human” and “not God.” *Id.*

Respondent also introduced into evidence a document which listed his purchases of this product from the Sessions Specialty Company. RX 10. According to the document, between April 28, 2003, and February 18, 2005, Respondent purchased 225 units at a total cost of \$396.25. *Id.* Respondent’s last purchase of the item was in February 2005, when it obtained twenty-five units for which it paid \$36.25. *Id.*

Following the inspection, a DI visited three of Respondent’s customers. At the first store, the Westgate Market, the manager told the DI that there were “very few customers for the List I” products that the store obtained from Respondent, but that the customers “were repeat customers.” Tr. 36.

At the second store, the Sloan Center, which was a truck stop complex with both a large gas station and convenience store, the manager told the DI “that she was aware that all these * * * List I chemical products were used for methamphetamine.” *Id.* at 37. The manager also stated that the store had sold other products which are used in the illicit manufacture of methamphetamine including steel wool, matches, coffee filters, and that because “in her experience,” the products “were selling much too quickly” to be satisfying legitimate consumer demand, “she had removed [the products] from the shelves.” *Id.* at 37–38. The DI also testified that the manager had told him “about the only people that bought” the listed chemical products, but offered no further details regarding their characteristics. *Id.* at 37.

Finally, the DI visited the Tellico Pride, which was managed by a former police officer. *Id.* at 39. The manager told the DI that he knew “from his experience” as both a police officer and store manager that the ephedrine products the store sold were being used for methamphetamine production.⁸ *Id.* at 39.

The DI did not relate any of this information to Mr. Gregg. Tr. 71–72. Moreover, Mr. Gregg testified that none of his customers had ever told him that the combination ephedrine products he

sold were being diverted, *id.* at 202–03; and that he did not believe that his products were being diverted. *Id.* at 260. Mr. Gregg further stated that if a customer told him this, he would tell them to “call the officials” and he “would not sell to that customer.” *Id.* at 203.⁹

On cross-examination, Mr. Gregg maintained that he would periodically ask his customers if they have repeat customers and told them not to sell more than two thirty-six count blister packs to a customer. *Id.* at 322–23. He also did not recall any customer telling him that people were purchasing the products every other day, although he acknowledged that some customers had told him that people were buying the products either once or twice a week. *Id.* at 323–24. He further maintained that he told his stores that they should not sell to persons who showed up every day. *Id.* at 325.

As evidence of his efforts to prevent diversion, Mr. Gregg provided posters to some of his customers which listed products that could be diverted into meth. production. See RX 7. Moreover, even prior to the enactment of the Meth Free Tennessee Act, Mr. Gregg had provided to most of his ephedrine customers “hundreds of * * * acrylic cases” for storing the products, which are placed “behind the counter.” Tr. 192–193. Mr. Gregg testified that he placed stickers inside the cabinets which stated that customers could only purchase “two bottles a day” and that the products could not be sold to minors. *Id.* at 196. Mr. Gregg maintained that he would stamp his sales invoices with the following statement: “Please limit a customer two bottles of ephedrine per day.” *Id.*; see also RX 12.

Furthermore, following the passage of the Meth Free Tennessee Act, which prohibited sales of tablet-form listed chemical products, Respondent retrieved the products from his customers and sold them to stores in neighboring States where the products were still legal. Tr. 202. Nor is it disputed that Respondent provides adequate security for the products at its registered location. Finally, Respondent offered evidence that it is conducting weekly audits of its handling of list I

chemical products, *id.* at 213–14, and Respondent has never been issued a warning letter regarding its handling of the products.

Respondent’s Sales Levels and the Market for List I Chemicals

The Government’s principal allegation in this proceeding is that Respondent was selling combination ephedrine products at levels that far exceed legitimate demand for the products for their approved therapeutic use as a bronchodilator, and that the products Respondent sells are likely being diverted. See Order to Show Cause at 4. As proof of this allegation, the Government submitted a declaration from an expert witness which concluded that “the vast majority of American consumers” purchase non-prescription drug products at pharmacies, supermarkets, large discount merchandisers, or through electronic shopping/mail-order establishments. GX 10, at 5 (declaration of Jonathan Robbin). Relatedly, the expert stated that convenience stores and gas stations such as Respondent’s customers “constitute [the] nontraditional market for the sale of * * * non-prescription drug pseudoephedrine products.” *Id.* at 6.

In this declaration (which was initially prepared five years earlier for a proceeding which involved a different Tennessee wholesaler), the expert further concluded that “the normal expected retail sale of pseudoephedrine (hcl) tablets in a convenience store may range between \$10 and \$30 per month, with an average of about \$20 per month,” and that the average store would spend “about \$12 per month acquiring an inventory of pseudoephedrine (hcl) tablets at wholesale from a distributor.” *Id.* at 8–9. The expert also stated that a sale of pseudoephedrine by a convenience store “of over \$100 a month * * * would be expected to occur in random sampling about once in a million raised to the tenth power, a number nearly equal to a count of all the atoms in the universe.” *Id.* at 8.

The expert further opined that sales of combination ephedrine products are about one-fourth the amount of pseudoephedrine sales and thus sales of ephedrine at the same level as pseudoephedrine sales are considerably less likely to be for legitimate demand than sales of pseudoephedrine. *Id.* at 10–11. The expert thus concluded that sales of listed chemical products in

⁸ The DI also visited a law enforcement station located in the Cherokee National Forest, which was approximately ten miles from the Tellico Pride store. Tr. 40–41. There, the DI was told that the authorities had found six sites where waste created by illicit methamphetamine manufacturers had been dumped. *Id.* at 40–41.

⁹ Mr. Gregg further testified that he did not become aware of the risk that combination ephedrine products could be diverted until the spring of 2005, when the DIs explained this to him, and the State of Tennessee enacted the Meth Free Tennessee Act. *Id.* at 261. Respondent also introduced into evidence several posters (which he provided to his customers) directed at retail store employees which listed various items used to make methamphetamine including ephedrine. See RX 7. Mr. Gregg’s testimony certainly pushes the limits of plausibility.

amounts similar to Respondent's sales¹⁰ are inconsistent with legitimate demand for the products. *Id.* at 11.

Notably, the expert's declaration contains no explanation as to his basis for concluding that ephedrine sales are only one-fourth of pseudoephedrine sales. *See generally id.* at 1–12. Moreover, after the record closed in this matter, the expert's methodology for calculating the sales levels of ephedrine was challenged in another proceeding and found wanting. *See Novelty Distributors, Inc.*, 73 FR 52689, 52693–94 (2008).

It is true that in this matter, Respondent did not raise similar challenges to the expert's methodology.¹¹ The Agency cannot, however, ignore the ultimate finding in *Novelty* which rejected the expert's conclusions as to the expected sales range of ephedrine products. Moreover, since the issuance of the *Novelty* decision, the Government has not offered any briefing as to why it would still be appropriate to adopt the expert's conclusions.¹² I therefore conclude that the expert's declaration does not constitute substantial evidence as to the expected sales range of ephedrine products to meet legitimate demand at convenience stores and gas stations. *See* 5 U.S.C. § 556(d).

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical "may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). Moreover, under section 303(h), "[t]he Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest." 21 U.S.C. 823(h). In making the public interest determination, Congress directed that the following factors be considered:

(1) maintenance by the applicant of effective controls against diversion of listed

chemicals into other than legitimate channels;

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

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

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

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

Id. § 823(h).

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

The Government, however, bears the burden of proof. 21 CFR 1301.44(d). Having considered the entire record in this matter, I conclude that the Government has not established that Respondent does not maintain effective controls against diversion. Moreover, while I find that Respondent violated Federal law when it sold the Lover's Roses even after he became aware that this item is used to smoke illicit drugs, I conclude that this single violation, which involved a nominal amount of this item, does not support the revocation of its registration. Based on the extensive evidence of Respondent's efforts to responsibly comply with Federal and state laws, I conclude that Respondent's registration should be suspended but that the suspension should be stayed for a period of probation.

Factor One—The Maintenance of Effective Controls Against Diversion

It is undisputed that Respondent maintains adequate security with respect to the storage of listed chemicals at its registered location. In the Show Cause Order, the Government alleged, however, that Respondent did not maintain effective controls against diversion for two additional reasons: (1) an audit performed during the March 2005 inspection found "substantial underage and overages" for several products, and (2) Respondent's sales of combination ephedrine products were "inconsistent with the known legitimate market and known end-user demand for products of this type," and therefore

Respondent "is serving an illegitimate market for these products." Show Cause Order at 3–4.

Neither of these allegations is supported by substantial evidence. As for the allegations pertaining to the audit, while the record establishes that an audit was conducted during the March 2005 inspection, the Government did offer the audit results into evidence. Accordingly, there is no basis to conclude that Respondent does not maintain adequate "systems for monitoring the receipt, distribution and disposition" of the List I products it distributes. *See* 21 CFR 1309.71(b)(8). The allegation is therefore rejected.

The Government also argues that Respondent was distributing combination ephedrine products in quantities that greatly exceed legitimate demand for these products at convenience stores, small markets and gas stations, and that its sales levels are consistent with diversion of the products into the illicit manufacture of methamphetamine. *See* Gov. Exceptions at 3–9. Moreover, the Government contends that even though Respondent complied with Tennessee law by ceasing its distribution of tablet-form products and selling only gel-caps to its Tennessee customers, even those sales are excessive. *See* Gov. Exceptions at 6–9 (listing Respondent's average monthly sales of gel cap products).

The Government's theory is based on expert testimony, which was credited in other cases, regarding the average monthly retail sale of ephedrine products at convenience stores and the statistical improbability that various sales levels were consistent with legitimate demand. However, as explained above, in *Novelty Distributors*, I found that the methodology used by the Government's expert in determining these figures was unreliable. I further concluded that the expert's figures for the average monthly sale and the statistical improbability of various sales of ephedrine to meet legitimate demand were not supported by substantial evidence.

Here, the Government relies on the expert's written testimony, which putting aside that it primarily addressed pseudoephedrine and offered nothing more than a conclusory assertion as to the level of ephedrine sales, appears to have been based on the same methodology which I rejected in *Novelty*.¹³ I therefore again conclude

¹⁰ The expert did not review any data pertaining to Respondent.

¹¹ Respondent did, however, argue that the declaration should be given "minimal consideration" because it was executed in September 2003, the expert did not review "any information concerning" Respondent, and it was "not based upon the most recent statistical figures available." Resp. Proposed Findings at 19.

¹² Nor has the Government sought a remand to put on additional evidence as to the expected sales range to meet legitimate demand.

¹³ It is noted that the expert's methodology involves various steps and that some of the problems identified with respect to ephedrine (such as the expert's purported use of consumer survey data which did not report any information specific to ephedrine, *see* 73 FR at 52693–94), may not be

that the Government's figures as to the monthly expected sales range to meet legitimate demand (and the statistical improbability of certain sales levels in legitimate commerce) are not supported by substantial evidence. Consistent with these findings, I am compelled to reject the Government's contention that Respondent's sales of gel-cap ephedrine products "are far in excess of any legitimate market for the product" and "that the products are being diverted to the illicit manufacture of methamphetamine."¹⁴ Gov. Exceptions at 5; see also Show Cause Order at 3–4.

It is true that the Government's evidence included testimony regarding the hearsay statements of two store managers which raise the suspicion that Respondent's products were being diverted by customers of those stores. But there is no evidence that the managers ever related their suspicions to Respondent, and Mr. Gregg testified that he would cut off sales to a customer if the customer told him that the products were being diverted.¹⁵ Relatedly, while in 2003, Respondent had submitted—at the Agency's request—a report regarding its estimated sales of list I products at each of its customers, no one at the Agency ever raised any objection regarding the quantities it was selling.

Nor did the Government introduce any evidence to question the credibility of Mr. Gregg's testimony that he had stopped selling bottled pseudoephedrine and sold only two tablet packages of this product upon being told by a DI years earlier that these products were dangerous and that the DI had not mentioned combination ephedrine products as raising the same concern. Finally, the record establishes that Respondent attempted to educate its customers regarding diversion and provided special cases to them for storing the products and had done so years before the enactment of laws requiring that they be kept either behind

the counter or in a locked case. See 21 U.S.C. § 830(e)(1)(A). In sum, the record as a whole does not establish that Respondent has failed to maintain effective controls against diversion.

Factor Two—Respondent's Compliance With Applicable Laws

The Government further maintains that Respondent violated Federal law because he knowingly sold drug paraphernalia (*i.e.*, the Love Roses). Gov. Proposed Findings at 8 (citing 21 U.S.C. 863). According to the testimony of a DI, this product is easily modified and used to smoke such substances as crack cocaine and methamphetamine. Moreover, at the hearing, Mr. Gregg acknowledged that shortly before the March 2005 inspection and his final sale of the product, he had become aware that the product was used to smoke crack. Notwithstanding this information, Respondent sold his remaining supply which amounted to approximately twenty-five of the Lover's Roses and stopped carrying the product.

The ALJ rejected the Government's argument as "tenuous," noting that under Federal law the term "drug paraphernalia" is defined as an item "primarily intended or designed for use in ingesting, inhaling, or otherwise introducing [controlled substances] into the human body." ALJ at 33 (quoting 21 U.S.C. 863(d)). According to the ALJ, "the primary purpose of a love rose appears to be decorative in nature * * * [and] [t]hus, this product was not primarily manufactured or designed to be used for the ingestion of a controlled substance." *Id.* (quoting Tr. 218) (testimony of Mr. Gregg; "when it first started out, all it was, was a cute little rose in a tube").

The ALJ, however, failed to acknowledge Supreme Court precedent interpreting the same statutory language which was used in the since repealed statute, 21 U.S.C. § 857. See *Posters 'N' Things, Ltd. v. United States*, 511 U.S. 513, 516 n.5 (1994).¹⁶ In *Posters 'N' Things*, the Court explained that Section 863(d) "identifies two categories of drug paraphernalia: items 'primarily intended * * * for use' with controlled substances and items 'designed for use' with such substances." *Id.* at 518. With respect to the latter category, the Court explained that "[a]n item is 'designed

for use' * * * if it 'is principally used with illegal drugs by virtue of its objective features, *i.e.*, features designed by the manufacturer.'" *Id.* (quoting *Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 501 (1982)).

As for the "primarily intended * * * for use" language, the Court acknowledged that the term "could refer to the intent of nondefendants, including manufacturers, distributors, retailers, buyers or users." *Id.* at 519. Based on its analysis of the statute's text and structure, the Court concluded that the term "is to be understood objectively and refers generally to an item's likely use." *Id.* at 521. The Court further explained that where an item has multiple uses, "it is the likely use of customers generally, [and] not [of] any particular customer, that can render a multiple-use item drug paraphernalia." *Id.* at 522 n.11.

While the Court construed section 857 as imposing a scienter requirement of knowledge, the Court held that "the knowledge standard in this context [does not] require knowledge on the defendant's part that a particular customer actually will use an item of drug paraphernalia with illegal drugs." *Id.* at 524. The Court further explained that "[i]t is sufficient that the defendant be aware that *customers in general are likely to use the merchandise with drugs*. Therefore, the Government must establish that the defendant knew that the items at issue are likely to be used with illegal drugs." *Id.* (emphasis added) (citing *United States v. United States Gypsum Co.*, 438 U.S. 422, 444 (1978) ("knowledge of 'probable consequences' sufficient for conviction")).¹⁷

The ALJ's reasoning that an item is not "drug paraphernalia," unless it was "primarily manufactured or designed to be used for the ingestion of a controlled substance," ALJ at 33, ignores the Supreme Court's holding that section 863(d) identifies two different categories of drug paraphernalia and that the "primarily intended * * * for use" category "refers generally to an item's likely use" by those who use it. 511 U.S. at 521. Applying this standard, the evidence establishes that a Love Rose's likely use is to smoke illicit drugs and that Respondent sold the products

a valid criticism of the methodology as it is applied to pseudoephedrine (because there may be more extensive data). Even so—and ignoring that the declaration discusses pseudoephedrine and not ephedrine (the chemical at issue in this case)—the expert's declaration contains none of the underlying data and calculations such as the number of stores used in determining the average sales per store.

¹⁴ It is further noted that while the Government calculated the average monthly purchase of Respondent's various List I customers, it did not calculate the mean and standard deviation for all stores and did not show any instances in which sales to particular stores greatly exceeded what its typical customer purchases. See 73 FR at 52700.

¹⁵ Indeed, the Government's figures for Respondent's monthly sales to the two stores do not stand out as suggesting that diversion was occurring.

¹⁶ As the Supreme Court explained in *Posters 'N' Things*: "The language of § 863 is identical to that of former § 857 except in the general description of the offense." 511 U.S. at 516 n.5. Of note, section 863 expanded the scope of prohibited acts with respect to drug paraphernalia and did not alter the definition of the term "drug paraphernalia." See *id.* Accordingly, the Court's interpretation of the term applies here.

¹⁷ See also *United States v. Mishra*, 979 F.2d 301, 307 (3d Cir. 1992) ("Government must prove that defendant 'contemplated, or reasonably expected under the circumstances, that the item sold or offered for sale would be used with illegal drugs'") (quoted at 511 U.S. at 524 n.13); *United States v. Schneiderman*, 968 F.2d 1564, 1567 (2d Cir. 1992) ("Government must prove that defendant 'knew there was a strong probability the items would be so used.'") (quoted at 511 U.S. at 524 n.13).

knowing that they were “likely to be used with illegal drugs.” *Id.* at 524.

At the outset, it should be noted that Congress expressly included in the definition of “drug paraphernalia,” a list of items which “constitute[*e*] *per se* drug paraphernalia.” *Id.* at 519. Of relevance here, Congress included in this list “metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens.” 21 U.S.C. 863(d). As the record shows, a Love Rose is nothing more than a small and fake flower inserted in a glass pipe, Tr. 33; that the pipe contains a flower does not make it any less a pipe.¹⁸ See *Posters ‘N’ Things*, 511 U.S. at 518 (observing that certain items “including bongs, cocaine freebase kits, and certain kinds of pipes, have no other use besides contrived ones (such as use of a bong as a flower vase)”). The item thus falls within the statutory definition of “drug paraphernalia.” See 21 U.S.C. 863(d).

Furthermore, even if the Love Rose does not fall strictly within the “list of * * * items constituting *per se* drug paraphernalia,” 511 U.S. at 519, there was ample evidence establishing that the item’s “likely use” is to ingest illicit drugs. *Id.* at 521. An agency Investigator testified that the Lover’s Roses are “commonly referred to as crack pipes,” and that they are “used to smoke crack” and methamphetamine. Tr. 34; *cf.* Sharon Tubbs, *A Crack Pipe by Any Other Name*, St. Petersburg Times (Aug. 10, 2001) (Floridian Section) (“The outsider assumes the rose tubes are meant to attract the impulse buyer who picks up a chintzy gift for his sweetie. But for addicts, the buy is anything but an impulse. Addicts go to stores looking for rose tubes, calling them ‘stems’—street talk for [a] crack pipe.”).

The DI further explained the ease with which this item is adapted for use as a crack or meth. pipe. *Id.* Finally, it is undisputed that at the time of the inspection—and before he sold his final stock—Mr. Gregg was aware of what this item was used for. *Id.* at 35. Indeed, Mr. Gregg testified that several of his customers had told him what the item was used for. *Id.* at 292. Thus, at the time he sold his remaining supply, Mr. Gregg was “aware that customers in general [we]re likely to use the merchandise with drugs.” 511 U.S. at 524.

Contrary to the ALJ’s reasoning, ALJ at 34, once Mr. Gregg became aware of the product’s likely use, it was unlawful for him to sell it. As for the ALJ’s

¹⁸ Indeed, even if one is cheap, if one is intent on expressing his/her affection for a loved one, there are plenty of other ways of doing so such as buying a real flower and not a fake one.

rational that “at some point the responsibility for the *misuse* of the * * * product * * * must rest upon the person * * * illegally ingesting a controlled substances through * * * the tube,” *id.*, Congress, by prohibiting the knowing sale of drug paraphernalia, has concluded otherwise. I thus hold that Respondent violated federal law when it sold its remaining stock of love roses. 21 U.S.C. 863(a)(1).

The record establishes, however, that Respondent’s violation involved only the sale of a small quantity of this item, which was likely no more than twenty-five units (and for which Respondent paid \$ 36.25). RX 10. Moreover, it is undisputed that Respondent stopped selling the product after this sale. Furthermore, other evidence suggests that Respondent has promptly complied with the requirement of recently enacted state and federal laws. See Tr. 224–25. Accordingly, while Respondent’s violation of 21 U.S.C. § 863(a) cannot be condoned, the limited nature of the violation and Respondent’s overall record of compliance with applicable laws does not support the conclusion that its continued registration is inconsistent with the public interest.¹⁹

Factor Four—Respondent’s Experience in the Distribution of Chemicals

Respondent has been registered since 1998. During this period, it has never been issued a warning letter and the record does not establish any other deficiencies in its handling of list I chemicals.²⁰ Furthermore, with the exception of the violation discussed above, the record indicates that Respondent has been attentive to his responsibilities as a registrant.

For example, it is undisputed that upon being told that bottled pseudoephedrine was a dangerous product, Respondent stopped carrying the product and limited his sales to two-tablet packages. When Tennessee banned tablet-form products, Respondent retrieved the products from his customers.

Moreover, Respondent voluntarily submitted to the Agency information regarding its sales of the products and

¹⁹ It is further noted that neither Respondent, nor its owner, has been convicted of an offense related to controlled substances or listed chemicals.

²⁰ Based on her finding that Respondent sold excessive quantities of listed chemical products, the ALJ concluded that “absent any change in marketing or product line, this factor would weigh in favor of revocation.” ALJ at 37. Because I conclude that the Government’s figures as to the expected sales range and probability of various sales levels are not supported by substantial evidence, I reject the ALJ’s conclusion with respect to factor four.

no one from the Agency ever objected to the quantities of products it was selling. Respondent also provided posters from Tennessee Meth Watch (a program of the Tennessee Bureau of Investigation) and the Southeast Tennessee Methamphetamine Task Force which identified numerous products which are used in the illicit manufacture of methamphetamine. RX 7. In addition, Respondent took steps—long before they were required by state or federal law—to protect the products from theft at his customers.

While proof that Respondent was selling quantities of products that are consistent diversion would outweigh all of the above and would support an adverse finding under this factor, as explained above, the Government has not met its burden of proof on this allegation. I therefore conclude that this factor supports the continuation of Respondent’s registration.

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

At the hearing, a DI testified that it was agency policy to seek the revocation of the registration issued to any person or entity which distributes listed chemicals to the non-traditional market. Tr. 82. Based on this testimony, Respondent contends that the Agency is in violation of the Administrative Procedure Act (APA) because it has adopted a substantive “rule for effecting automatic registration revocations of all entities distributing List I products to gray market entities” without engaging in notice and comment rulemaking under 5 U.S.C. 553. Resp. Prop. Findings at 25–26.

Relatedly, in an appendix, the ALJ opined that there is an “agency-wide policy of revoking the registrations of ‘gray market’ distributors” and that this policy “is substantive, rather than procedural, in nature.” ALJ at 46. Continuing, the ALJ recommended “that the [A]gency should not proceed against listed chemical distributors on such a ‘rule’ alone because the [A]gency has not” engaged in notice and comment rulemaking. ALJ at 47 (emphasis added).

Neither Respondent’s argument nor the ALJ’s reasoning is persuasive. As an initial matter, at most the evidence establishes a policy of seeking the revocation of such registrations.²¹ See Tr. 141 (testimony of DI acknowledging that “the mere fact that someone sells on the graymarket is cause for DEA to

²¹ Notably, in its Exceptions, the Government disputes that there is any such policy. Exceptions at 10–11. (arguing that “[t]he ALJ had no basis on which to assume that DEA has a policy of revoking

seek [the] revocation of their registration”) (emphasis added). A policy of seeking the revocation of the registrations issued to a particular class of registrants is not, however, the same as a policy of revoking such registrations. Indeed, to equate the former with the latter ignores that the ultimate decision in any proceeding under section 304 of the Act does not rest with those who prosecute but with the Deputy Administrator. See 28 CFR 0.104 (Appendix section 7(h)).

Moreover, contrary to the understanding of both Respondent and the ALJ, the above described policy is not a rule within the meaning of the APA. As numerous courts have recognized, a policy does not constitute a rule unless it establishes a “binding norm” or “a standard of conduct which has the force of law.” See *Pacific Gas & Elec. Co. v. FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974). The policy merely reflects the decision of those with prosecutorial authority to focus the Agency’s resources on a particular and serious aspect of the diversion problem. As such, it “does not establish a ‘binding norm[,]’” which has the force and effect “of law.” *Id.* at 38; see also *Center for Auto Safety v. NHTSA*, 452 F.3d 798, 806 (D.C. Cir. 2006) (noting that one line of inquiry “considers the effects of an agency’s action, inquiring whether the agency has ‘(1) imposed any rights and obligations, or (2) genuinely [left] the agency and its decision-makers free to exercise discretion’”) (other citation omitted).²² Notably, in her appendix, the ALJ did not cite to any decision of this Agency which holds that the mere act of distributing to the non-traditional market constitutes a *per se* ground for revocation of an existing registration or the denial of an application.²³

the * * * registrations of all List I chemical distributors that distribute * * * in the gray market. * * * The opinions of non-managerial employees attesting to the existence of an agency policy, without more, can hardly be a sufficient basis for a fact-finder to make a formal finding, or in this case, to simply assume, that a federal agency has implemented a substantial policy.”)

²²The other line of inquiry focuses on the “[A]gency expressed intentions.” *Center for Auto Safety*, 452 F.3d at 798. As the Government points out, “[t]here was no evidence that [the DIs] were authorized to speak on behalf of the agency regarding agency policy, that the two employees had any involvement in the formulation of the alleged policy, or were in managerial or executive positions.” Exceptions at 11. Thus, the employees’ testimony does not express the Agency’s intention.

²³In her appendix, the ALJ observed that she “could find no agency final order where * * * the DEA registration was continued for a DEA-registered distributor selling listed chemical products to the ‘gray market,’ as defined by the” Agency. ALJ at 37. The absence of any such decision does not establish that there is such a rule because each case is decided with respect to the five factors set forth in 21 U.S.C. § 823(h).

Indeed, in this matter, the Government does not argue that Respondent’s registration should be revoked solely because it distributes to the non-traditional market. Rather, the Government relied primarily on what it alleged were various practices of Respondent (such as excessive sales and poor recordkeeping) that increased the risk that its products were being diverted. Moreover, were the Government to seek revocation solely on the basis that a registrant was distributing to the non-traditional market (rather than on the basis that its policies and practices were increasing the risk of diversion), it would be required “to present evidence and reasoning supporting its” position, *Center for Auto Safety*, 452 F.3d at 807 (quoting *Pacific Gas*, 506 F.2d at 38); and the registrant would be entitled to challenge the Government’s evidence and reasoning.²⁴

To be sure, based on its experience, DEA has frequently recognized that the distribution of listed chemical products through non-traditional retailers presents a heightened risk of diversion and has considered this to be an important factor in the public interest analysis. See, e.g., *Joy’s Ideas*, 70 FR 33195, 33199 (2005). But as this case demonstrates, there is no *per se* rule prohibiting the distribution of listed chemicals to the non-traditional market and subjecting a registration to revocation for the mere act of distributing to the non-traditional market.

Sanction

In her decision, the ALJ concluded that the Agency had met its burden of

²⁴Relying on *Ford Motor Co. v. FTC*, 673 F.2d 1008, 1009 (9th Cir. 1982), Respondent asserts that because the purported rule “creates a general and widespread standard for revocation” it must be “subject[ed] to notice and comment rulemaking.” Resp. Proposed Findings at 25 & n.70. Respondent’s reliance on *Ford* is peculiar because it is widely recognized as a sport case.

As several leading commentators have explained: “The Ninth Circuit’s decision in *Ford* almost certainly is an aberration. It has been severely criticized. It is inconsistent with both [*SEC v. Chenery*, 352 U.S. 194 (1947)], and [*NLRB v. Bell Aerospace Co.*, 415 U.S. 199 (1974)]. Indeed, even the Ninth Circuit seems not to have followed it in subsequent cases.” Richard J. Pierce, et al., *Administrative Law and Process* 295 (1985).

Moreover, the preeminent treatise squarely states that *Ford* was “wrongly decided and should not be followed.” I Richard J. Pierce, *Administrative Law Treatise* § 6.9, at 384 (4th ed. 2002). As this authority explains: “The [*Ford*] court rested its holding on the proposition that ‘an agency must proceed by rulemaking if it seeks to change the law and establish rules of widespread application.’ That proposition is not supportable in Supreme Court decisions; rather it is directly contradicted by such decisions and is inconsistent with the routine practice of all courts and agencies.” *Id.*

proof by showing that Respondent was selling excessive quantities of listed chemicals. Based in part on Respondent’s compliance with the Meth Free Tennessee Act,²⁵ the ALJ further concluded that the revocation of Respondent’s registration would be too severe a sanction and recommended that its registration be continued subject to two conditions—(1) that Respondent be limited to selling only soft-gel products, and (2) that Respondent consent to periodic inspections by the Agency based on a Notice of Inspection and without a warrant.

In *Janet L. Thornton*, 73 FR 50354, 50356 (2008), I explained that “[w]hile in some instances, this Agency has placed restrictions on a practitioner’s registration, such restrictions must be related to what the Government has alleged and proved in any case.” The ALJ’s proposed conditions were based on her finding that Respondent had engaged in excessive sales. But having rejected the Government’s proof as insufficient to support this allegation, there is no basis to impose these conditions.

The only violation proved on this record is Respondent’s sale of drug paraphernalia (*i.e.*, the Love Roses). But as found above, the evidence supports the conclusion that Respondent committed only a single violation of the statute, and the violation involved only a nominal amount. Moreover, it is undisputed that following this sale, Respondent stopped carrying the item.

Respondent’s sale of any amount of this product (once Mr. Gregg learned how it was being used) violated Federal law and is a criminal offense. Indeed, it is stunning that Mr. Gregg sold this product after being told by several of his customers that it was being used to smoke crack cocaine. Contrary to his testimony that because he is “not God,” he could not determine why some of the persons he saw buying the product were

²⁵The ALJ also based her recommendation on what she maintained was “the lack of evidence in this record showing that soft-gel listed * * * products have actually been made into methamphetamine at illicit laboratories.” ALJ at 41. I have previously rejected this reasoning, and would have done so again had the Government proved that Respondent was selling quantities of products that are consistent with diversion. See *Holloway Distributing*, 72 FR 42118, 42126 (2007); *T. Young Associates*, 71 FR 60567, 60573 (2006). As I have previously explained, “‘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.’ This Agency is not required to wait until the diversion of gelcap and liquid forms of pseudoephedrine reach epidemic proportions before acting to protect the public interest.” *Holloway Distributing*, 72 FR at 42126 (quoting 71 FR at 60573).

doing so, this Agency does not expect its registrants to possess divine powers. It does, however, expect that its registrants exercise common sense and act responsibly.

Respondent's and Mr. Gregg's violation in selling this product cannot be condoned. I therefore conclude that Respondent's registration should be suspended for a period of six months. However, in light of the total record in this case, which establishes that Respondent has otherwise attempted to obey applicable laws and regulations, I conclude that the suspension should be stayed for a period of three years at which time the suspension will be rescinded provided Respondent does not commit any further violation of federal or state laws or regulations related to listed chemicals or controlled substances.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that the application of Gregg & Son Distributors to renew its DEA Certificate of Registration be, and it hereby is, granted. I further order that the DEA Certificate of Registration issued to Gregg & Son Distributors be, and it hereby is suspended for a period of six months, but that the suspension shall be stayed for a period of three years from the date of this Order provided Respondent complies with all applicable laws and regulations as set forth above. This Order is effective immediately.

Dated: April 3, 2009.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E9-8621 Filed 4-14-09; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Meeting of the CJIS Advisory Policy Board

AGENCY: Federal Bureau of Investigation (FBI), Department of Justice.

ACTION: Meeting Notice.

SUMMARY: The purpose of this notice is to announce the meeting of the Criminal Justice Information Services (CJIS) Advisory Policy Board (APB). The CJIS APB is a Federal advisory committee established pursuant to the Federal Advisory Committee Act (FACA). This meeting announcement is being published as required by section 10 of the FACA.

The CJIS APB is responsible for reviewing policy issues and appropriate technical and operational issues related to the programs administered by the FBI's CJIS Division, and thereafter, making appropriate recommendations to the FBI Director. The programs administered by the CJIS Division are the Integrated Automated Fingerprint Identification System, the Interstate Identification Index, Law Enforcement Online, National Crime Information Center, the National Instant Criminal Background Check System, the National Incident-Based Reporting System, Law Enforcement National Data Exchange, and Uniform Crime Reporting.

The meeting will be open to the public on a first-come, first-seated basis. Any member of the public wishing to file a written statement concerning the CJIS Division programs or wishing to address this session should notify Senior CJIS Advisor Roy G. Weise at (304) 625-2730 at least 24 hours prior to the start of the session. The notification should contain the requestor's name, corporate designation, and consumer affiliation or government designation along with a short statement describing the topic to be addressed and the time needed for the presentation. A requestor will ordinarily be allowed no more than 15 minutes to present a topic.

DATES AND TIMES: The APB will meet in open session from 8:30 a.m. until 5 p.m., on June 4-5, 2009.

ADDRESSES: The meeting will take place at the Gaylord National, 201 Waterfront Street, National Harbor, Maryland, (301) 965-2300.

FOR FURTHER INFORMATION CONTACT: Inquiries may be addressed to Ms. Lori A. Kemp, Management and Program Analyst, Advisory Groups Management Unit, Liaison, Advisory, Training and Statistics Section, FBI CJIS Division; Module C3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306-0149; telephone (304) 625-2619; facsimile (304) 625-5090.

Dated: April 1, 2009.

Roy G. Weise,
Senior CJIS Advisor, Criminal Justice Information Services Division, Federal Bureau of Investigation.

[FR Doc. E9-8490 Filed 4-14-09; 8:45 am]

BILLING CODE 4410-02-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08-58]

John B. Freitas, D.O.; Revocation of Registration

On August 29, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to John B. Freitas, D.O. (Respondent), of Carthage, Missouri. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BF2847715, which authorizes him to dispense controlled substances in schedules II through V as a practitioner, as well as the denial of any pending application to renew or modify the registration, on the ground that Respondent lacks authority to dispense controlled substances in Missouri, the State in which he is registered with DEA. Show Cause Order at 1.

Respondent timely requested a hearing on the allegation; the matter was placed on the docket of the Agency's Administrative Law Judges (ALJ). Thereafter, the Government moved for summary disposition. Motion for Summary Disp. at 1. The basis of the motion was that Respondent's Missouri Controlled Substances Registration automatically terminated when Respondent ceased practicing at the location where he held his State registration and "did not notify the [State] of [his] change of address or a new Missouri practice location." *Id.* at Attachment 1 (Letter of Michael R. Boeger, Asst. Administrator, Missouri Bureau of Narcotics & Dangerous Drugs, to Dr. John Freitas (May 13, 2008)).¹

Thereafter, Respondent filed his response to the Government's motion. Therein, Respondent acknowledged the State BNDD's letter and further stated that he "does not deny that he no longer has the authority to handle controlled substances in the State of Missouri." Respondent's Response to Gov.'s Mot. for Summ. Disp. at 1. Respondent argued, however, that his state registration had not been "suspended, revoked, or denied under Missouri law by the BNDD," and that under 21 U.S.C. 824(a)(3), DEA's authority to revoke is limited to those situations in which a registrant's State authority has been

¹ According to the letter, the State "ha[d] received information that [Respondent's] last day of practicing at that location was the[e] date of [his] overdose on March 25, 2008," and "had received written documentation that [Respondent's] privileges were terminated at that location on March 26, 2008." Gov. Motion at Attachment 1.