

that Respondent had violated its corresponding responsibility under Federal law by filling prescriptions which were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *Id.* More specifically, the Order alleged that Respondent had “acquired over 15 million dosage units of” such drugs as Didrex and phentermine, which are schedule III and IV controlled substances respectively, and that Respondent was dispensing “huge amounts of dosage units to persons who” obtained prescriptions through the Internet and “who [were] never actually seen or examined by a physician.” *Id.* at 8.

Respondent timely requested a hearing. The matter was placed on the docket of the Agency’s Administrative Law Judges (ALJ), and a hearing was held on March 27 through 29, 2006, at which both parties elicited the testimony of witnesses and introduced various documents into evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument. Moreover, on October 11, 2007, the ALJ invited the parties to submit additional briefs in light of my decision in *United Prescription Services, Inc.*, 72 FR 50397 (2007); both parties did so.

Thereafter, on March 10, 2008, the ALJ issued her recommended decision. In her decision, the ALJ found that Respondent and its owner had repeatedly violated Federal law by filling prescriptions for controlled substances which it had reason to know were unlawful. ALJ at 64–69. The ALJ also found that Respondent’s owner had failed to accept responsibility for her misconduct. *Id.* at 70. The ALJ thus concluded that “Respondent’s continued registration would be inconsistent with the public interest,” and recommended that I revoke its registration and deny any pending applications. *Id.*

On May 2, 2008, Respondent filed exceptions to the ALJ decision. Shortly thereafter, the record was forwarded to me for final agency action.

During the course of reviewing the record, my office determined that on August 12, 2008, Respondent had been acquired by Walgreens. On the same day, Respondent also surrendered its registration certificate, as well as its order forms (DEA Form 222), to the Agency’s Philadelphia Field Division Office. Letter of Charlotte J. Lopacki, R.Ph., to DEA Philadelphia Field Div. Office (August 12, 2008). There is, however, no evidence that Respondent completed a voluntary surrender form.

Based on these acts, I find that Respondent has discontinued business. Under 21 CFR 1301.52(a), “the registration of any person shall terminate if and when such person * * * discontinues business or professional practice.” Accordingly, I will declare that Respondent’s registration has terminated with an effective date of August 12, 2008. And because there are no pending applications before the Agency, I further hold that the Show Cause proceeding is now moot.²

Order

Pursuant to the authority vested in me under 5 U.S.C. 554(e), as well as 28 CFR 0.100(b) & 0.104, I hereby declare terminated as of August 12, 2008, DEA Certificate of Registration, BB5209223, issued to Budget Pharmacy and Wellness Center, of Feasterville, Pennsylvania. Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I further order that the Order to Show Cause issued to Budget Pharmacy and Wellness Center be, and it hereby is, dismissed. This Order is effective immediately.

Dated: April 3, 2009.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–50]

Sylvester A. Nathan; Dismissal of Proceeding

On June 25, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Sylvester A. Nathan, M.D. (Respondent), of Woodridge, Illinois. The Show Cause Order proposed the revocation of Respondent’s DEA Certificate of Registration, AN1430343, which authorized him to dispense controlled substances as a practitioner, and the denial of any pending applications to renew or modify the registration, on the ground that the Illinois Department of Professional Regulation had suspended

² While I have raised the issue of Respondent’s registration status *sua sponte*, in the event Respondent seeks to refute the factual basis upon which I rely, it may do so by filing a motion for reconsideration within fifteen days of the date of service of this Order, which shall begin on the date the Order is mailed.

Respondent’s “state license to handle controlled substances,” and that Respondent is therefore without authority to dispense controlled substances in the State in which he holds his registration. *Id.* at 1.

Respondent timely requested a hearing on the allegations and sought a five-month long continuance of the proceeding. Thereafter, the Government moved to deny Respondent’s request for a continuance and for summary disposition. The basis for the summary disposition motion was that Respondent’s state medical license had been suspended. As support for the motion, the Government attached: (1) A copy of a July 25, 2007 order of the Illinois Department of Financial and Professional Regulation (IDFPR), which indefinitely suspended Respondent’s Illinois Physician and Surgeon’s Certificate until he provided proof that he has passed the Special Purpose Examination (SPEX); and (2) a July 8, 2008 printout of Respondent’s Physician Profile from the IDFPR’s Web site, which indicated that the status of Respondent’s license was “suspended.”

Thereafter, the ALJ issued an Order for Respondent’s Response. On August 11, 2008, Respondent submitted his response in which he acknowledged that since July 25, 2007, he “has no authority to prescribe, handle or [d]ispense any [c]ontrolled medical substances in the state” of Illinois. With the submission, Respondent also enclosed his DEA Certificate of Registration but indicated on the document that it was being “returned under protest.”

Shortly thereafter, the ALJ granted the Government’s motion for summary disposition. ALJ at 6. The ALJ noted that there was no dispute that “Respondent is not authorized to practice medicine in Illinois” and thus could not “prescribe controlled substance in that State.” *Id.* at 5. Applying the Agency’s longstanding interpretation that the Controlled Substances Act precludes the continuation of a registration if the practitioner no longer holds authority to dispense controlled substances in the State in which he practices medicine, *id.* (collecting cases); the ALJ granted the Government’s motion and recommended that Respondent’s registration be revoked and that any pending application be denied.

Respondent did not file exceptions to the ALJ’s decision. On September 11, 2008, the record was forwarded to me for final agency action. Having considered the entire record and having taken official notice of the registration

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.