by renewal to the Drug Enforcement Administration (DEA) as a bulk manufacturer of Cocaine (9041), a basic class of controlled substance listed in schedule II.

The company plans to manufacture small quantities of the above listed controlled substance for distribution to its customers for the purpose of research.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than December 27, 2010.


Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–27037 Filed 10–25–10; 8:45 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufactures holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on July 9, 2010, Noramco, Inc., 1440 Olympic Drive, Athens, Georgia 30601, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thebaine (9333)</td>
<td>II</td>
</tr>
<tr>
<td>Tapentadol (9780)</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans to import Thebaine (9333) analytical reference standards for distribution to its customers. The company plans to import an intermediate form of Tapentadol (9780) to bulk manufacture Tapentadol for distribution to its customers.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than November 26, 2010.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.


Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–27035 Filed 10–26–10; 8:45 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated October 21, 2009 and published in the Federal Register on October 28, 2009, (74 FR 55586), Archimica, Inc., 2460 W. Bennett Street, Springfield, Missouri 65807–1229, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Tapentadol (9780), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance in bulk for distribution to its customers.

One comment objecting to the granting of registration as a bulk manufacturer of the basic class of controlled substance listed to this applicant was received. However, after a thorough review of this matter, DEA has concluded that the issues raised in the comment and objection do not warrant the denial of this application.

DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Archimica, Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Archimica, Inc. to ensure that the company’s registration is consistent with the public interest. The investigation has included inspection and testing of the company’s physical security systems, verification of the company’s compliance with state and local laws, and a review of the company’s background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.


Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–27032 Filed 10–25–10; 8:45 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Steven B. Brown, M.D.; Revocation of Registration

On May 13, 2010, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration (“Order”) to Steven B. Brown, M.D. (“Registrant”), of Wilton Manors and Pompano Beach, Florida. The Order proposed the revocation of Registrant’s DEA Certificates of Registration, BB2972140 and FB1490349, as well as the denial of any pending applications for the renewal or modification of both registrations, on the ground that his “continued registrations are inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(i).” Order at 1.

The Order alleged the Registrant “issued illegal prescriptions for oxycodone, a Schedule II controlled
substance, for no legitimate medical purpose and outside the course of [his] professional practice." Id. at 1–2 (citing 21 U.S.C. 841(a) and 21 CFR 1306.04(a)). More specifically, the Order alleged that Registrant “prescribed oxycodone 30 mg. tablets in amounts as high as 180 dosage units to patients” and that he “received half the dosage units back from the patients after the illegal prescription was filled and dispensed.” Id. at 2. The Order also alleged that on March 27, 2010, “[a]s a result of [Registrant’s] illegal prescribing and [his] illegal possession of controlled substances,” Registrant “was arrested by the Broward County Sheriff’s Office.” Id. Moreover, the Order alleged that on April 28, 2010, Registrant “illegally possessed amphetamine, a Schedule II controlled substance possessed amphetamine, a Schedule II controlled substance.” Id.

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In March 2010, DEA and the Broward County Sheriff’s Office (“BSO”) received information from a confidential source (“CS”) that Registrant was issuing prescriptions for oxycodone 30 mg. to the CS and providing her with money to fill the prescriptions; in exchange, the CS gave Registrant half of the pills she obtained. Declaration of Diversion Investigator (ID), at 1–2. According to the CS, Registrant had been treating her for chronic pain for the last four years. However, after two years, Registrant proposed that he would write her prescriptions for 160 tablets of oxycodone 30 mg. and give her the money to pay for them “if the CS would give half the pills back to him.” Id.; see also Stat. Susp. Order, at 2. The CS agreed to the arrangement. Id.

Each month for two years, Registrant wrote the CS prescriptions for up to 180 tablets of oxycodone 30 mg. and gave her the money to pay for them; the CS would then provide Registrant with half of the pills she obtained. Declaration, at 2. Registrant told the CS to fill the prescriptions at local pharmacies and not at his clinic. Id. The CS also related to the Investigator that Registrant was abusing oxycodone and Dilaudid. Id. at 2.

At about 6:16 p.m. on March 27, 2010, the CS, under the direction of a BSO officer and a DI, made a consensually recorded telephone call to Registrant to arrange a delivery of oxycodone to him. During the call, Registrant twice asked the CS if she had split the oxycodone up; the CS answered affirmatively. The CS and Registrant then agreed to meet in the parking lot of a local fast food restaurant.

During the delivery, which was observed by several law enforcement officers, the CS wore a recording device. Id. Upon meeting, Registrant asked the CS if she “want[ed] one of these hits?” and stated: “Oh their good.” The CS replied “Yeah” and Registrant then said: “You know what I’m talking about right? It’s Percocet liquid.” The CS replied that she knew “that’s the Oxysol” but added that she did not want any because it would upset her stomach.

Acknowledging that the drug would do so, Registrant stated: “You know what I do? To make it taste better I put Wyler’s Raspberry in it.” Registrant then added: “It’s so good.” The CS, however, again said that she did not want any of the drug. The CS then gave the oxycodone to Registrant, who gave her eighty dollars. The CS left, and shortly thereafter, Registrant was arrested and charged with trafficking in oxycodone.

On May 5, 2010, the State Surgeon General, Florida Department of Health (DOH), issued an Order of Emergency Suspension of License which immediately suspended Registrant’s physician’s license. State Suspension Order, at 1, 12. The Order alleged that Registrant “violated Section 458.331(1)(d)” of the Florida Statutes “by prescribing to [three individuals] with no medical records justifying why the prescriptions were being written.” Id. at 10, as well as “by prescribing * * * a legend drug, including any controlled substance, other than in the course of the physician’s professional practice.” Id. at 11.

The State Suspension Order further alleged “that [Registrant] has shown a disregard for the safety of the public with his practice of prescribing medications to patients with no medical records to justify why the prescriptions were being written” and that his “practice was especially egregious in that he was using his relationship as a physician with a patient to divert medication for his own use.” Id. Accordingly, the State Suspension Order concluded that Registrant’s “actions clearly constitute prescribing outside the practice of medicine and present such an immediate, serious danger to the public health, safety or welfare that nothing short of the immediate suspension of the State license to practice medicine will protect the public from this danger.” Id.

Discussion

Section 304(a) of the Controlled Substances Act (“CSA”) provides that a “registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has had his State license suspended, revoked, or denied by competent State authority and is no longer authorized by

Findings

Registrant is a physician licensed by the State of Florida. He is the holder of two DEA Certificates of Registration: (1) BB2972140 (as well as XB2972140), at the registered address of 1749 N.E. 26th Street, Suite A, Wilton Manors, Florida; and (2) FB1490349, at the registered address of 605 East Atlantic Blvd, Pompano Beach, Florida. Both registrations do not expire until July 31, 2012.

Registrant practiced pain management at his Pompano Beach registered practice. Order of Emergency Suspension of License, at 2. In re: Steven Barry Brown, M.D., (Fla. Dep’t of Health, Nos. 2010–06419, 2010–07923) (hereinafter, State Susp. Order). He is also registered under Florida law as a dispensing practitioner; this authorizes him to order and dispense controlled substances in the State.

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State law to engage in the * * * dispensing of controlled substances,” 21 U.S.C. 824(a)(3), or “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.” Id. § 824(a)(4). With respect to the latter ground for revocation, the CSA directs that the following factors be considered:

1. The recommendation of the appropriate State licensing board or professional disciplinary authority.

2. The applicant’s experience in dispensing * * * controlled substances.

3. The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

4. Compliance with applicable State, Federal, or local laws relating to controlled substances.

5. Such other conduct which may threaten the public health and safety.


The public interest “factors are * * * considered in the disjunctive.” Robert A. Leslie, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. Id. 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); see also Morall v DEA, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

As explained below, the investigative record clearly shows that Registrant’s experience in dispensing controlled substances and compliance with applicable laws is characterized by his unlawful use of his prescribing authority to obtain controlled substances for his personal use. Moreover, the record also shows that by virtue of the State Suspension Order, Registrant no longer has authority under Florida law to dispense controlled substances and thus, he no longer meets an essential requirement for holding a DEA registration. I will therefore order that Registrant’s Certificate of Registration be revoked.

The Public Interest Grounds

Factors Two, Four, and Five:

Registrant’s Experience in Dispensing Controlled Substances, Record of Compliance With Applicable Controlled Substance Laws, and Such Other Conduct Which May Threaten Public Health and Safety

Under a longstanding DEA regulation, a prescription for a controlled substance is not effective unless it is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 CFR 1306.04(a). This regulation further provides that an “order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of * * * 21 U.S.C. 829 * * * and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” Id. See also 21 U.S.C. 802(10) (Defining the term “dispense” as meaning “to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance.”)

As the Supreme Court recently explained, “the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” Gonzales v Oregon, 546 U.S. 243, 274 (2006) (citing United States v Moore, 423 U.S. 122, 135, 143 (1975)).

As found above, in order to obtain drugs for his own use, Registrant entered into an agreement with the CS to provide her with monthly prescriptions for 160 to 180 tablets of oxycodone 30 mg. Registrant paid for the prescriptions in exchange for the CS’s providing him with half of the pills. Registrant wrote the prescriptions on a monthly basis for a two-year period.

While during this period, Registrant may have been treating the CS for legitimate chronic pain (although with another drug), it is clear that Registrant’s primary purpose in writing these prescriptions was to obtain drugs that he then abused. Each of the prescriptions Registrant wrote thus violated 21 CFR 1306.04(a) and constituted an unlawful distribution of a controlled substance. See 21 U.S.C. 841(a)(1) (“Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally * * * to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.”). See also Michael F. Myers, 72 FR 36464, 36486 (2007) (finding Respondent “engaged in the criminal distribution of controlled substances in violation of 21 U.S.C. 841” where Registrant “issued [a] person prescriptions for hydrocodone on a monthly basis * * * [and the] person admitted * * * that he took very few hydrocodone tablets and regularly provided Respondent with 60 of them”).

Under the CSA, it is also “unlawful for any person knowingly or intentionally * * * to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.” 21 U.S.C. 843(a)(3). Even assuming that the CS required her share of the oxycodone to treat a legitimate medical condition, by writing prescriptions in excess of the CS’s legitimate medical needs and for the purpose of obtaining the drugs for his own use, Registrant obtained possession of controlled substances by “deception[] or subterfuge” and violated Federal law.

Moreover, Florida prohibits the prescribing of “inappropriate quantities” of legend drugs, including controlled substances. Fla. Stat. 458.331(1)(g). Again, even assuming that the CS had a legitimate medical need for her share of the oxycodone, Registrant violated Florida law because the prescriptions he issued to her clearly exceeded the quantity necessary to treat her condition and were issued in those quantities so that he could obtain drugs for his own use.

Additionally, DEA has long held that a practitioner’s self-abuse of controlled substances constitutes “conduct which may threaten public health and safety.” 21 U.S.C. 823(f)(5). See Tony T. Bui, 75 FR 49979, 49990 (2010); Kenneth Wayne Green, Jr., 59 FR 51453 (1994); David E. Trawick, 53 FR 5326 (1988). In addition to the evidence showing that Registrant issued prescriptions to the CS to obtain controlled substances for his own use, the evidence also shows that during the March 27, 2010 meeting with the CS, he offered her a bit of liquid oxycodone, stating “Oh their good,” and then explained how he made it more palatable to ingest. Thus, it is clear that Registrant is a drug abuser and a threat to public health and safety.2

I, therefore, conclude that the evidence pertinent to Registrant’s experience in dispensing controlled substances (factor two), his record of compliance with Federal and State laws related to controlled substances (factor two, four, and five), and such other conduct which may threaten public health and safety (factor five) is dispositive of the public interest grounds.

2 I conclude that it is not necessary to make findings under factor one because Registrant’s loss of his State authority will be considered separately in this Decision.

As for factor three, while there is evidence that Registrant was arrested on drug charges, there is no evidence as to the disposition of the charges. Nor is there any evidence establishing that Registrant has otherwise been convicted of any offenses within the purview of factor three. However, DEA has repeatedly held that the absence of any convictions under factor three is not dispositive of the public interest inquiry. See, e.g., Edmund Chein, 72 FR 6590, 6593 n.22 (2007).
four), and such other conduct which may threaten public health and safety (factor five), establishes that he has committed acts which render his continued registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4). This finding provides reason alone to revoke Registrant’s registrations and to deny any pending applications to renew or modify his registrations.

The Loss of State Authority Ground

Under the CSA, a practitioner must possess authority to dispense controlled substances under the laws of the State in which he engages in his professional practice in order to obtain and maintain a DEA registration. See 21 U.S.C. 802(21) (defining the term “practitioner” as a person “licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he [practitioner] practices * * * [or] administer * * * a controlled substance”, id. § 823(f) (“The Attorney General shall register practitioners * * * to dispense * * * controlled substances * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices."). As these provisions make plain, possessing authority under State law to handle controlled substances is an essential condition for holding a DEA registration. See John B. Freitas, 74 FR 17524, 17525 (2009); Dominick A. Ricci, at 51104, 51105 (1993); Bobby Watts, 53 FR 11919, 11920 (1988). DEA, has therefore, held repeatedly that the CSA requires the revocation of a registration issued to a practitioner whose State authority has been suspended or revoked. David W. Wang, 72 FR 54297, 54298 (2007); Sheran Arden Yeates, 71 FR 39310, 39311 (2006); Dominick A. Ricci, 58 FR 51104, 51105 (1993); Bobby Watts, 53 FR 11919, 11920 (1988). See also id. § 824(a)(3) (a “registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has had his State license suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the * * * dispensing of controlled substances”). DEA has further held that revocation is warranted even where a practitioner’s State authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State’s action. See Robert Wayne Mosier, 75 FR 49950 (2010). For the same reason that I ordered the immediate suspension of Registrant’s DEA registrations, I conclude that the public interest requires that this Order be effective immediately.

The Show Cause Order alleged that the Oklahoma State Board of Medical Licensure had found that: (1) Respondent “prescribed or administered a drug (i.e., meperidine, a schedule II controlled substance, and hydrocodone, a schedule III controlled substance) or treatment without sufficient examination or the establishment of a valid physician patient relationship”; (2) Respondent “engaged in indiscriminate or excessive prescribing, dispensing or administering of controlled or narcotic drugs”; and (3) Respondent “prescribed, dispensed or administered controlled substances or narcotic drugs in excess of the amount considered good medical practice or prescribed, dispensed or administered controlled substances or narcotic drugs without medical need.” Id. at 1–2.

Next, the Show Cause Order alleged that on June 23, 2008, based on the Oklahoma Board’s action, the Medical Board of California “ordered the revocation of [Respondent’s] license to practice medicine in that state, effective July 23, 2008.” Id. at 2. Finally, the Order alleged that on July 7, 2008, Respondent “falsified” his application for renewal of his DEA registration “by answering ‘no’ to the question concerning whether [Respondent] had ever had a state professional license revoked or placed on probation or whether any such action was pending.” Id.

On December 16, 2008, the Show Cause Order was served on Respondent by certified mail to him at the address which he had recently given the Agency as his new registered location on his application to modify his registration. On January 29, 2009, Respondent’s counsel filed a request for a hearing and the matter was placed on the docket of the Agency’s Administrative Law Judges (ALJs). Thereafter, the ALJ requested that the parties address whether Respondent had timely requested a hearing. See Corrected Order Cancelling Hearing and Terminating Proceedings, at 1. Following receipt of the parties’ submissions, the ALJ found that Respondent’s request was not timely because it was not filed within 30 days of service of the Show Cause Order as required by 21 CFR 1301.43(a). Id. at 2. Because Respondent had not “provide[d] a basis upon which to find good cause,” the ALJ held that his failure to file a timely request constituted a waiver of his right to a hearing. Id. (citing 21 CFR 1301.43(d) and Brinton D. Gilsson, 72 FR 54296 (2007)). Accordingly, the ALJ canceled the scheduled hearing, terminated the proceedings, and directed that the