

applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending?" Mr. Arna marked "NO," and in the area provided for explaining any "YES" answer, wrote "None." *Id.*

On February 17, 2012, following a hearing before a state Administrative Law Judge (ALJ), the Secretary of the Illinois Department of Human Services issued a Final Order on Applicant's application for state licensure. *See In the Matter of Serenity Café* at 1, 11 DASA 001 (Ill. Dep't Hum. Servs., Feb. 17, 2012). Adopting the ALJ's findings and report, the Final Order denied Applicant's application for a state license to provide both Level I Adult and Adolescent Outpatient Treatment and Level II Adult and Adolescent Intensive Outpatient Treatment, DUI Evaluation, DUI Risk Education, and Methadone as Adjunct Services. *Id.*

Accordingly, because Applicant does not possess a valid Illinois license to provide substance abuse treatment, I find that Applicant is not currently authorized to dispense controlled substances in the State of Illinois, the State in which it seeks registration. *See 20 Ill. Comp. Stat. 301/15-5* (it is "unlawful for any person to provide treatment for alcoholism and other drug abuse or dependency . . . unless the person is licensed to do so by the Department"); Ill. Admin. Code tit. 77, 2060.201 ("Substance abuse treatment and intervention services * * * shall be licensed by the Department.").

Discussion

Under section 303(g) of the Controlled Substances Act (CSA), "practitioners who dispense narcotic drugs [in schedule II] to individuals for maintenance treatment * * * shall obtain annually a separate registration for that purpose." 21 U.S.C. 823(g)(1) (emphasis added). Moreover, this provision imposes as a requirement of registration, that the applicant meet three conditions, including that "the applicant is a practitioner who is determined by the Secretary to be qualified * * * to engage in the treatment with respect to which registration is sought." *Id.* 823(g)(1)(A) (emphasis added). Thus, it is clear that in order to obtain a registration authorizing the dispensing of schedule II narcotics such as methadone for maintenance treatment, the applicant must be (among other things), a

practitioner within the meaning of the CSA.¹

The CSA defines the term "practitioner" to mean "a physician * * * pharmacy, hospital or other person licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice." 21 U.S.C. 802(21). Likewise, in the case of practitioners, the CSA imposes, as a condition of registration, that it be currently authorized to dispense controlled substances under the laws of the State in which it engages in professional practice. *See id.* 823(f) ("The Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices."). Thus, DEA has long held that the possession of authority under state law to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration. *See David W. Wang*, 72 FR 54297, 54298 (2007); *Sheran Arden Yeates*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988).

As found above, the Illinois Department of Human Services has issued a final order denying Applicant's application for the state licenses required to dispense controlled substances for the purpose of providing maintenance treatment. Therefore, Applicant is not a "practitioner" within the meaning of the CSA, and thus, it is not entitled to be registered. *See 21 U.S.C. 802(21); 823(f); 823(g).* Accordingly, its application will be denied.²

¹ Likewise, the requirements of section 303(g)(1) "are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B). 21 U.S.C. 823(g)(2)(A) (emphasis added). This provision requires that the "the practitioner submit to the Secretary [of HHS] a notification of the intent of the practitioner to begin dispensing the drugs or combinations for" maintenance or detoxification treatment, "as well as to certify that "[t]he practitioner is a qualifying physician," that "the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services," and that "[t]he total number of such patients of the practitioner at any one time will not exceed the applicable number." *Id.* 823(g)(2)(B) (emphasis added). Moreover, a practitioner's notification to the Secretary must "identify] the registration issued for the practitioner pursuant to subsection (f) of this section." *Id.* 823(g)(2)(D)(i)(II). *See also* 21 CFR 1301.28.

² Because it is clear that Applicant is not entitled to be registered, it is not necessary to decide

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 823(g)(1) & (2), as well as 28 CFR 0.100(b), I order that the application of Serenity Café for a DEA Certificate of Registration as a Narcotic Treatment Program, be, and it hereby is, denied. This Order is effective July 12, 2012.

Dated: June 4, 2012.

Michele M. Leonhart,
Administrator.

[FR Doc. 2012-14291 Filed 6-11-12; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bill Alexander, M.D.; Decision and Order

On September 22, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order To Show Cause to Bill Alexander, M.D. (Applicant), of Porter, Texas. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration as a practitioner in schedules II through V, on the ground that his "registration would be inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order alleged that on December 3, 2010, Applicant applied for a practitioner's registration in schedules II–V at the location of 24420 FM 1314, Suite 101, Porter, Texas. *Id.* The Show Cause Order then alleged that on or about June 18, 2009, Applicant unlawfully possessed 64 kilograms of marijuana, a schedule I controlled substance, in violation of both federal and state law. *Id.* at 2 (citing 21 U.S.C. 841(a)(1) and Texas Health & Safety Code Ann. 481.121(b)(5)).

Next, the Show Cause Order alleged that on or about June 18, 2009, Applicant told law enforcement agents that he was transporting the marijuana for a drug dealer, and that he had transported over a dozen such loads of marijuana in the past. *Id.* The Order further alleged that Applicant told the agents that he was addicted to and used crack cocaine, a schedule I controlled substance.¹ *Id.*

The Show Cause Order also alleged that on or about February 4, 2011, the Texas Medical Board entered a Corrective Order against Applicant's medical license. *Id.* According to the

¹ whether denial of its application is warranted under the public interest standard of 21 U.S.C. 823(f).

allegations, the Texas Board found that Applicant prescribed controlled substances to individuals without holding a valid Texas Controlled Substances Registration, in violation of state law. *Id.* (citing Tex. Health & Safety Code Ann. 481.061(a)).

The Show Cause Order further alleged that during various interviews with DEA Investigators, Applicant stated his desire to open a pain management clinic in order to make money. *Id.* According to the allegations, Applicant stated his “belief that the purpose of a pain management clinic was to give addicts their prescriptions because other doctors won’t do it.” *Id.*

The Show Cause Order, which also notified Applicant of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for doing either, and the consequence for failing to do either, *id.* at 2 (citing 21 CFR 1301.43), was served on Applicant by registered mail addressed to him at the address he provided on his application. While the return receipt card did not include a delivery date, Applicant subsequently confirmed to Government Counsel that he received the Order on September 26, 2011. GX 4; Request for Final Action, at 2.

Since the date of service of the Order, thirty days have now passed and neither Applicant, nor anyone purporting to represent him, has requested a hearing or submitted a written statement in lieu of a hearing. I therefore find that Applicant has waived his right to a hearing or to submit a written statement in lieu of a hearing, and issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) and (e). I make the following additional findings of fact.

Findings

Applicant’s Licensure and Registration Status

Applicant is a physician licensed by the Texas Medical Board (hereinafter, the Board). GX 6. On February 4, 2011, a Quality Assurance Panel of the Board issued a Corrective Order to Applicant. *Id.* Therein, the Board found that notwithstanding that Applicant had allowed his Texas Controlled Substance Registration to expire on October 31, 2008, he had continued to write prescriptions for controlled substances through October 21, 2009, when his state license was renewed. *Id.* The Order imposed an administrative penalty in the amount of \$500 against Applicant. *Id.* at 1–2 (citing Tex. Occ. Code Ann. 164.002(a) and (d), and 164.053(a)(1)).

Applicant previously held DEA Certificate of Registration BA0549177, which authorized him to dispense controlled substances in schedules II through V, as a practitioner, at the registered location of 1406 Wilson Road, Conroe, TX 77304. GX 2. This registration expired by its terms on June 30, 2003. *Id.*

On March 30, 2004, Applicant was granted Certificate of Registration BA8721765, which also authorized him to dispense controlled substances in schedules II through V, as a practitioner, at the registered location of 350 South Adams, Eagle Pass, TX 78852. This registration expired by its terms on June 30, 2010. *Id.*

On December 3, 2010, Applicant submitted a new application for a practitioner’s registration in schedules II through V, through the Office of Diversion Control’s Web site. It is this application which is at issue in this proceeding.

Evidence Regarding the Substantive Allegations

On June 18, 2009, following a traffic stop, Applicant was arrested by a Texas Highway Patrol Officer for possession of marijuana, a schedule I controlled substance. GX 5. At the time of his arrest, the Trooper conducted a consensual search of Applicant’s vehicle, during which he found two large black suitcases which contained marijuana and a small black toiletry bag which contained several homemade smoking pipes. *Id.* at 4–5. Regarding the pipes, which the Trooper identified as drug paraphernalia, the Trooper asked Applicant what he used them for; Applicant stated: “To smoke.” *Id.* The Trooper then asked Applicant what he smoked; Applicant replied: “Crack,” which is a schedule II controlled substance. *Id.* Respondent was then arrested; however, he was not criminally charged.

On December 6, 2010, a DEA Diversion Investigator (DI) began an investigation of Applicant’s December 3, 2010 application for a DEA registration. GX 7 (DI’s affidavit). According to the DI’s affidavit, because Applicant cooperated with another ongoing law enforcement investigation, he was never criminally charged in connection with his arrest for possession of marijuana on June 18, 2009. *Id.*

The DI stated that during a phone conversation on January 11, 2011, Applicant admitted that at the time of his June 2009 arrest, which he characterized as a mistake, he was transporting marijuana for a drug trafficking organization because he needed the money. *Id.* at 2. Applicant

told the DI he planned to open a medical clinic, with other practitioners, which would specialize in orthopedic surgery and pain management. *Id.* He stated that his desire to open a pain management clinic was only because he wanted to make money and that he would “do anything to make money.” *Id.*

During a subsequent in-person interview, Applicant told the DIs that he closed his last medical practice, an orthopedic surgery center, in 2008. *Id.* He also admitted that he had abused crack cocaine in the past, but had stopped using crack cocaine in 2009 after having a heart attack. *Id.* However, Applicant never underwent a drug treatment program. *Id.*

Applicant told the DIs that after closing his medical practice in late 2008, he agreed to transport marijuana for a drug organization. *Id.* Applicant admitted to having driven loads of marijuana from Eagle Creek or Del Rio, Texas to either San Antonio or Austin because he was having financial problems and he would “do anything not to lose [his] property.” *Id.* He also admitted that he transported such loads approximately every other weekend from the end of 2008 until he was arrested in June 2009, but he was uncertain as to the exact number of loads he had delivered. *Id.* at 2–3. Applicant stated that he was paid \$50 per pound, and that he usually received \$3,000 to \$5,000 per load of marijuana. *Id.* at 3.

Applicant told the DIs that he only wanted to open a pain clinic to share the overhead costs of a medical clinic with other practitioners, that he did not have any formal pain management training, and that he “hated those kinds of patients.” *Id.* at 3. Moreover, he then stated that pain management clinics were good because they served individuals who were addicted to pain medication without “bogging down other clinics asking for pain pills.” *Id.* When asked by the DIs what he would do when he had twenty patients waiting for their prescriptions, Applicant responded that “if their doctors gave them a prescription and they’re hooked, if they’re a functioning patient, probably give it to them. What else are you gonna [sic] do with them?” *Id.*

Upon being told by the DI that she was recommending the denial of his application based on his previous involvement with transporting large quantities of marijuana and his intention to open a pain clinic, Applicant asked the DI if she thought that “there’s a proper way” to manage a pain clinic and make sure everything was done correctly. *Id.* When the DI said

that she did not think it was proper to provide prescriptions to addicts, Applicant replied: “What do you think pain management clinics are for? They give addicts their prescriptions because other doctors won’t do it!” *Id.* at 3–4.

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner’s registration may be denied upon a determination “that the issuance of such registration would be inconsistent with the public interest.” 21 U.S.C. 823(f). In making the public interest determination in the case of a practitioner, Congress directed 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.

Id. “[T]hese 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 deny an application.” *Id.*; see also *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009). While I must consider each factor, I am “not required to make findings as to all of the factors.” *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005).

With respect to a practitioner’s registration, the Government has the burden of proving by substantial evidence that granting a registration would be inconsistent with the public interest. See 21 CFR 1301.44(d).² As no DEA regulation provides that the entry of a default is a consequence of the waiver of the right to a hearing, the Government must therefore support its

² As found above, Applicant neither requested a hearing nor submitted a written statement explaining his position on the matters of fact and law asserted. By contrast, in a contested case, where the Government satisfies its *prima facie* burden, as for example, by showing that an applicant has committed acts which are inconsistent with the public interest, the burden then shifts to the Applicant to demonstrate why he can be entrusted with a registration. *Medicine Shoppe-Jonesborough*, 73 FR 363, 387 (2008).

proposed action with substantial evidence.

In this matter, I have considered all of the factors and conclude that the evidence relevant to Respondent’s experience in dispensing controlled substances (factor two), his compliance with applicable laws related to controlled substances (factor four), and his having engaged in other conduct which may threaten the public health and safety (factor five), conclusively establishes that granting his application would be “inconsistent with the public interest.” 21 U.S.C. 823(f).

Factors One and Three—The Recommendation of the State Licensing Board and the Applicant’s Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution or Dispensing of Controlled Substances

As found above, the Board found that Applicant dispensed controlled substances for nearly a year without the requisite State controlled substance registration. However, the Board took no action against Applicant’s medical license other than to impose a \$500 administrative penalty and he thus retains an active State medical license. Also, Applicant apparently still holds a valid Texas Controlled Substance Registration.

However, while the CSA makes holding authority to dispense controlled substances a condition of obtaining a DEA registration, it is not dispositive of the public interest inquiry. Rather, in enacting the public interest amendments to the CSA, Congress vested this Agency with “a separate oversight responsibility [apart from that which exists in State authorities] with respect to the handling of controlled substances.” *Mortimer B. Levin*, 55 FR 8209, 8210 (1990). DEA has therefore long recognized that it has “a statutory obligation to make its independent determination as to whether the granting of [a registration] would be in the public interest.” *Id.* Accordingly, “DEA has long held * * * that a State’s failure to take action against an Applicant’s medical license [or State controlled substance registration] is not dispositive in determining whether the continuation of a registration is in the public interest.” *Jayam Krishna-Iyer*, 74 FR 459, 461 (2009); see also *Levin*, 55 FR at 8210 (holding that practitioner’s reinstatement by state board “is not dispositive” in public interest inquiry). Thus, that neither the Texas Medical Board nor Texas Department of Public Safety has suspended or revoked Applicant’s medical license or controlled substance registration is of no

consequence in determining whether his continued registration is consistent with the public interest.

Likewise, the fact that Applicant has not been convicted of an offense falling within factor three, notwithstanding his arrest and admission that on numerous occasions he transported large quantities of marijuana for a drug trafficking organization, is not dispositive. As previously explained, and as this case demonstrates, there are a variety of reasons why a person who has engaged in criminal conduct may not have been convicted, let alone charged with a criminal offense. See *Dewey C. MacKay*, 75 FR 49956, 49973 (2010). Accordingly, I find that factor three is not dispositive of whether granting Applicant’s application would be consistent with the public interest.

Factors Two and Four—Applicant’s Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

The Texas Board found that Applicant allowed his Texas Controlled Substance Registration to expire on October 31, 2008, and yet continued to write controlled substance prescriptions in violation of Texas law until he renewed his license on October 21, 2009. GX 6, at 1–2. This was also a violation of federal law.

Under a DEA regulation, “[a] prescription for a controlled substance may be issued only by an individual practitioner who is * * * authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession.” 21 CFR 1306.03(a)(1). By issuing prescriptions when he did not possess state authority, Respondent thus violated the CSA as well. 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 * * * dispense * * * a controlled substance[.]”).

In addition, Applicant admitted to the DIs that on numerous occasions, he illegally transported large quantities of marijuana for a drug trafficking organization and was paid to do so. GX 7, at 2–3. This conduct also violated 21 U.S.C. 841(a)(1), which prohibits both the knowing or intentional distribution of a controlled substance, as well as the possession of a controlled substance with the intent to distribute.

Finally, Applicant admitted that he abused crack cocaine. GX 7, at 2. This conduct violated 21 U.S.C. 844(a), which makes it “unlawful for any person knowingly or intentionally to possess a controlled substance unless

such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as authorized by" the CSA or the Controlled Substances Import Export Act. In addition, Respondent's conduct violated various provisions of state law. *See Tex. Health & Safety Code 481.115(a) and 481.121(b)(5).* Thus, the evidence with respect to factors two and four provides ample reason to deny Applicant's application.³

Factor Five—Such Other Conduct Which May Threaten the Public Health and Safety

As found above, during the consensual search of Applicant's vehicle, a Texas Highway Patrol Officer found several home-made pipes, and upon being questioned as to what he used them for, Applicant admitted that he smoked crack cocaine. Also, Applicant admitted to DEA Investigators that he had previously abused crack cocaine. While Applicant later claimed that he had stopped using crack after suffering a heart attack, he also stated that he never underwent drug rehabilitation treatment.

DEA has "long held that a practitioner's self-abuse of a controlled substance can be considered under Factor Five even if there is no evidence that [he] abused his prescription-writing authority or otherwise engaged in an unlawful distribution to others." *See Scott D. Fedosky*, 76 FR 71375, 71378 (2011). *See also Tony T. Bui*, 75 FR 49979, 49989–90 (2010) (collecting cases); *David E. Trawick*, 53 FR 5326, 5327 (1988). Thus, even if there was no other evidence of misconduct on the part of Applicant, his self-abuse of crack cocaine would by, itself, constitute conduct which threatens public health and safety and renders his proposed

³ As evidence of his likely non-compliance with applicable laws related to controlled substances, I note that during his interviews with DEA Investigators regarding the purpose of his proposed registration, Applicant stated that he wanted to open a pain clinic "only because he wanted to make money, and that he would do anything to make money." *Id.* at 2. Moreover, Applicant expressed the view that pain clinics were good because they served individuals who were addicted to pain medication without "bogging down other clinics asking for pain pills." GX 7, at 3. Subsequently, Applicant stated "what do you think pain management clinics are for? They give addicts their prescriptions because other doctors won't do it!" *Id.* at 3–4. Putting aside the misconduct proven on this record, Applicant's comments do not inspire confidence that he would comply with federal requirements such as 21 CFR 1306.04(a), which requires that a prescription for a controlled substance be issued only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

registration "inconsistent with the public interest." *Id.* 823(f).

Conclusion

Based on Applicant's misconduct in issuing prescriptions without the requisite state authority, *see* 21 CFR 1306.03(a), his admitted transportation of marijuana for a drug trafficking organization, *see* 21 U.S.C. 841(a)(1), and his self-abuse of crack cocaine, I conclude that Applicant's registration would be "inconsistent with the public interest." *Id.* 823(f). Accordingly, his application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Bill Alexander, M.D., for a DEA Certificate of Registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: June 2, 2012.

**Michele M. Leonhart,
Administrator.**

[FR Doc. 2012–14316 Filed 6–11–12; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–51]

4 OTC, Inc.; Decision and Order

On September 22, 2011, Administrative Law Judge (ALJ) Gail A. Randall issued the attached Recommended Decision. Therein, the ALJ recommended that I deny Respondent's application for a Certificate of Registration as an importer of ephedrine, a list I chemical. Neither party filed exceptions to the decision.¹

Having considered the record as a whole, including the parties' briefs, I have decided to adopt the ALJ's findings of fact and conclusions of law except as explained below. Because I agree with the ALJ's conclusion that Respondent has failed to prove that the proposed importation of its combination ephedrine products is "necessary to provide for medical, scientific, or other legitimate purposes" and thus, it is not

¹ The ALJ initially issued a decision on July 22, 2011, to which both parties filed exceptions. However, after the record was forwarded to this Office, the ALJ requested that the record be returned. Subsequently, the ALJ re-issued her decision. Neither party filed exceptions to this decision. However, I have considered the exceptions which the parties submitted following the ALJ's issuance of her first opinion.

All citations to the ALJ's decision are to the slip opinion as originally issued by her which includes a cover page and table of contents.

entitled to the issuance of a rule under 21 U.S.C. 952(a)(1) authorizing the importation of such products, this alone is reason to adopt the ALJ's recommendation. ALJ at 54–57. I further agree with the ALJ's ultimate conclusion that Respondent's registration would be "inconsistent with the public interest." 21 U.S.C. 958(c)(2)(A); ALJ at 80–81. Accordingly, Respondent's application will be denied.

The Section 952 Analysis

As the ALJ noted, in 2006, Congress enacted the Combat Methamphetamine Epidemic Act of 2005 (CMEA), Public Law 109–177, 120 Stat. 256. Among the CMEA's provisions was section 715, 120 Stat. 264–65, which amended 21 U.S.C. 952(a) by adding the listed chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to those substances (*i.e.*, narcotic raw materials and coca leaves) for which importation is not authorized unless the Attorney General finds the amount "to be necessary to provide for medical, scientific, or other legitimate purposes." 21 U.S.C. 952(a)(1). Upon such a finding, the controlled substance or listed chemical "may be so imported under such regulations as the Attorney General shall prescribe." *Id.* 952(a).

In multiple cases involving applications for a registration to import a substance subject to section 952(a)(1), DEA has held that an applicant "cannot be registered as an importer of [such substance] unless the [Agency] finds that [it] will be allowed to import [the substance] pursuant to 21 U.S.C. 952(a)(1)." *Johnson Matthey, Inc.*, 67 FR 39041, 39042 (2002); *see also Chattem Chemicals, Inc.*, 71 FR 9834, 9835 (2006); *Penick Corp., Inc.*, 68 FR 6947, 6948 (2003). As previously explained, a finding that the proposed importation complies with section 952(a) is "a prerequisite to [an applicant's] registration as an importer" of a substance subject to this provision. *Roxane Laboratories, Inc.*, 63 FR 55891, 55892 (1998). Moreover, it is settled that because the applicant is the proponent of the rule authorizing a proposed importation of a substance subject to section 952(a)(1), "it must establish by a preponderance of the evidence that such a rule can be issued." *Johnson Matthey*, 67 FR at 39042; *see also Chattem*, 71 FR at 9835; *Penick*, 68 FR at 6948.

As the ALJ concluded, Respondent failed to establish by a preponderance of the evidence that its proposed importation of its combination ephedrine/guaifenesin product is "necessary to provide for medical, scientific, or other legitimate purposes."