

In this context, I am further guided by prior decisions before the DEA involving certificate holders whose state medical licenses have been revoked or suspended. On the issue of whether an evidentiary hearing is required, “it is well settled that when there is no question of material fact involved, there is no need for a plenary, administrative hearing.”²⁵ Under this guidance, the Government’s motion must be sustained unless a material fact question has been presented.

The Government argues that the sole determinative fact now before me is that Respondent’s medical license has been suspended by the Kentucky Medical Board. I agree. In order for a medical doctor to be authorized to administer controlled substances, he or she must meet the definition of “practitioner” as found in the Controlled Substances Act.²⁶ Such a person must be “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.”²⁷ Delegating to the Attorney General the authority to determine who may or may not be registered to perform these duties, Congress permitted such registration only “if the applicant is authorized to dispense * * * controlled substances under the laws of the state in which he practices.”²⁸

These two sources of authority complement the provision that is triggered when a registrant loses his or her state license to practice: where, as here, a registrant “has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the * * * dispensing of controlled substances,”²⁹ the registrant is no longer entitled to registration by the DEA. As cited by the Government in its Motion for Summary Disposition, there is substantial authority both through agency precedent and through decisions of courts in review of that precedent, holding that a petitioner’s DEA registration is dependent upon his or her license to practice medicine.³⁰ Under the doctrine before me, the

Government meets its burden of establishing grounds to revoke a registration upon sufficient proof establishing the registrant’s medical license has been suspended or revoked. That proof is in the record before me, and it warrants the summary revocation of Respondent’s DEA certificate.

I am mindful of the arguments raised by Respondent in his Reply to the Government’s Motion for Summary Disposition. At the outset, Respondent noted that he has not yet had an opportunity to present evidence to the Kentucky Medical Board, and urges that action by the DEA to revoke his registration wait until that process has run its course.³¹ Emphasizing the temporary nature of the Medical Board’s emergency order, Respondent asserts that the Board acted on the basis of evidence which, according to Respondent, is of questionable weight.³² Beyond the concerns raised about not having been permitted to challenge this evidence and about the accuracy or sufficiency of the evidence, Respondent criticizes the DEA investigation and complains about its undue influence on the Medical Board, all occurring without benefit of a hearing.³³

Some care should be taken to assure the parties that the actions taken in this administrative proceeding conform to constitutional requirements. Although he cites no authority in support of his claim, I have examined the parties’ contentions with an eye towards ensuring all tenets of due process have been adhered to. There is, however, no authority for me to evaluate the facts that underlie Respondent’s contentions. Those contentions are summarized in his Reply to the Government’s Motion for Summary Disposition. These generally describe his meritorious service as a physician and the extenuating circumstances that may have led to adverse outcomes for some of his patients.³⁴ While the details of these circumstances may well be of interest to the Kentucky Medical Board, the facts or allegations presented in his Reply are not material in the administrative proceedings now before the DEA. In the proceedings now before me, the only material question is answered by the stipulation that establishes the suspension of Respondent’s license. Further, and as is sufficiently set forth in the Government’s Motion for Summary Disposition, revocation of the DEA

certificate 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 at which he may ultimately prevail.”³⁵

Conclusion, Order, and Recommendation

I find there is no genuine dispute regarding the action taken by the Kentucky Medical Board, and that because of that action the Respondent’s medical license in Kentucky has been and remains suspended. I find no other material facts at issue, for the reasons set forth in the Government’s Motion for Summary Disposition. Accordingly, I *grant* the Government’s Motion for Summary Disposition.

Upon this finding, I *order* that this case be forwarded to the Deputy Assistant Administrator for final disposition. I *recommend* the Respondent’s DEA Certificate of Registration, Number AS6213172, be revoked.

Dated: February 4, 2013.

Christopher B. Mcneil,
Administrative Law Judge.

[FR Doc. 2013-07194 Filed 3-27-13; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13-13]

Pawan Kumar Jain, M.D.; Decision And Order

On February 12, 2013, Administrative Law Judge (ALJ) Gail A. Randall issued the attached recommended decision. Neither party filed exceptions to the decision. Having reviewed the entire record, I have decided to adopt the ALJ’s rulings, findings of fact, conclusions of law, and recommended Order.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BJ5128067, issued to Pawan Kumar Jain, M.D., be, and it hereby is, revoked. I further order that any pending application of Pawan Kumar Jain, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.

³⁵ Government’s Motion for Summary Disposition Jan. 8, 2013 at 4 (quoting *Kamal Tiwari, M.D.*, 76 FR 71604, 71606 (2011)).

v. Consolidated Mines & Smelting Co., Ltd., 455 F.2d 432, 453 (9th Cir. 1971)).

²⁵ See *Michael G. Dolin, M.D.*, 65 FR 5661 (2000); *Jesus R. Juarez, M.D.*, 62 FR 14945 (1997); see also *Philip E. Kirk, M.D.*, 48 FR 32887 (1983), *aff’d sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984).

²⁶ 21 U.S.C. 802(21).

²⁷ *Id.*

²⁸ 21 U.S.C. 823(f).

²⁹ 21 U.S.C. 824(a)(3).

³⁰ Government’s Motion for Summary Disposition Jan. 8, 2013 at 4, and cases cited therein.

³¹ Reply to the Government’s Motion for Summary Disposition Jan. 22, 2013 at 1.

³² *Id.* at 2.

³³ *Id.*

³⁴ *Id.* at 3-9 and 10-17.

Dated: March 21, 2013.

Michele M. Leonhart,
Administrator.

Dedra S. Curteman, Esq., for the
Government
Jeffrey C. Grass, Esq., for the Respondent

**Recommended Rulings, Findings of
Fact, Conclusions of Law, and Decision
of the Administrative Law Judge**

I. Facts

Gail A. Randall, Administrative Law Judge. The Deputy Assistant Administrator, Drug Enforcement Administration (“DEA” or “Government”), issued an Order to Show Cause (“Order”) dated December 13, 2012,¹ proposing to revoke the DEA Certificate of Registration, Number BJ5128067, of Pawan Kumar Jain, M.D., (“Dr. Jain” or “Respondent”), as a practitioner, pursuant to 21 U.S.C. 824(a)(3)–(4) (2006), and deny any pending applications for renewal or modification of such registration because the Respondent does “not have authority to practice medicine or handle controlled substances in the State of New Mexico” and Respondent’s “continued registration is inconsistent with the public interest.” [Order at 1].

Specifically, the Order alleged that the New Mexico State Medical Board took action against the Respondent on June 28, 2012. [*Id.*]. The Order further alleged that as a result of the action by the New Mexico State Medical Board, the Respondent is without authority to handle controlled substances in the state of New Mexico, the state in which the Respondent is registered with the DEA. [*Id.*] Thus, the DEA must revoke Respondent’s DEA registration based on his lack of authority to handle controlled substances in the state of New Mexico. [*Id.*]. Additionally, the Order alleged that on April 3, 2012, during the execution of a federal search warrant, DEA personnel located controlled substances and prescription bottles at the Respondent’s premises after the Respondent had previously stated on February 22, 2012, that he “did not order controlled substances for dispensing or administering at [his] registered location” nor did he maintain controlled substances on his premises. [*Id.* at 1–2]. In relation to this allegation, the Order asserted that the Respondent did not maintain an inventory log for the controlled substances located at his registered location and thus, he violated 21 CFR 1304.11(a). Lastly, the Order alleged that from June 2008 through

September 2011 at least twenty-one of the Respondent’s patients died as a result of ‘multiple drug toxicity.’ [*Id.* at 2]. Moreover, the Order alleged that a medical expert reviewed ten of the Respondent’s patient records, seven of which were deceased patients, and determined that the Respondent’s care deviated from the standard of care, and in some cases resulted in the death of the Respondent’s patients. [*Id.*]. In relation to this allegation, the Order stated that the Respondent provided strong and dangerous controlled substances to patients who posed a risk of diversion, the Respondent post-dated prescriptions, the Respondent failed to properly complete prescriptions, and the Respondent did not issue prescriptions for a legitimate medical purpose in the usual course of professional practice. [*Id.*].

On January 16, 2013, the Respondent, through counsel, filed a request for a hearing in the above-captioned matter. Concurrently with his request for hearing, Respondent filed a Motion for Stay of the Order to Show Cause Hearing (“Respondent’s Motion”). Therein, Respondent moved to stay the scheduled hearing in this matter pending the resolution of Respondent’s “Petition for Judicial Review of the New Mexico State Medical Board’s revocation of his medical license.” [Respondent’s Motion at 1]. Respondent argued that a stay of the administrative hearing will not harm the public interest because Dr. Jain is currently unable to handle controlled substances. [*Id.*].

On January 22, 2013, the Court issued an Order directing the Government to respond to Respondent’s Request for Hearing and Motion for Stay of the Hearing on or before January 29, 2013.

On January 28, 2013, the Government filed its Motion for Summary Disposition and Response to Respondent’s Request for Hearing and Motion for Stay of the Hearing (Government’s Motion’).² Therein, the Government opposed the Respondent’s Motion for Stay of the Hearing and moved this Court to summarily dismiss the above-captioned matter. [Government’s Motion at 1].

The Government argued that summary disposition is warranted in this case because the Respondent currently lacks authority to handle controlled substances in the State of New Mexico and thus lacks authority to

possess a DEA registration. [*Id.* at 2–3]. The Government attached to its motion, a Decision and Order from the New Mexico Medical Board, dated December 17, 2012, in which the New Mexico Medical Board revoked the Respondent’s medical license.³ [*Id.* at Exhibit C]. The Government argues, therefore, that in accordance with Agency precedent, the DEA is barred by statute from continuing the Respondent’s registration because his state medical license has been revoked. [*Id.* at 2–3]. In addition, the Government argues that summary disposition is appropriate even though the Respondent intends to contest the New Mexico Board’s decision to revoke his authority to practice medicine or handle controlled substances in the state of New Mexico. [*Id.* at 3–5]. The Government argues that summary disposition is warranted, even though the Respondent’s privileges may be reinstated at a later date, because Agency precedent allows for the revocation of a registrant’s registration when a state license has been suspended. [*Id.*]. Therefore, the Government requested that this Court grant its Motion for Summary Disposition and recommend that the Respondent’s DEA registration be revoked because the Respondent lacks state authority to handle controlled substances. [*Id.* at 5]. In addition, the Government requested that this Court deny Respondent’s Motion for Stay of the Hearing. [*Id.*].

On January 29, 2013, the Court issued an Order directing the Respondent to respond to Government’s Motion for Summary Disposition on or before February 5, 2013. The Respondent failed to respond to the Government’s Motion for Summary Disposition by the Court’s set date of February 5, 2013.

For the reasons set forth below, I will grant the Government’s Motion and recommend that the Administrator revoke the Respondent’s DEA Certificate of Registration. But, I note that, pursuant to 21 CFR 1301.13(a) (2012), the Respondent may apply for a new DEA Certificate of Registration at any time.

I will also deny the Respondent’s Motion for a Stay.

³In addition, the Government provided a June 28, 2012 Summary Suspension Order of the Respondent’s New Mexico license to practice as a “physician assistant” [*sic*] from the New Mexico Medical Board, *see* Government Motion at Exh. A, a July 6, 2012 Amended Summary Suspension Order of the Respondent’s New Mexico license to practice as a physician from the New Mexico Medical Board, *see* Government Motion at Exh. B, and a November 5, 2012 Hearing Officers Report from the New Mexico Medical Board, *see* Government Motion at Exh. D.

¹The Order to Show Cause was served on the Respondent on December 17, 2012. *See* Government’s Notice of Service.

²Government concurrently filed its Notice of Service, which stated that the December 13, 2012 Order to Show Cause was served on Respondent on December 17, 2012 by DEA investigators. *See* Government’s Notice of Service. Thus, the Respondent’s January 16, 2013 Request for Hearing was timely filed. *See* 21 CFR 1301.43(a) (2012).

II. Discussion

A. Respondent Currently Lacks Authority To Handle Controlled Substances In New Mexico

The DEA will not maintain a controlled substances registration if the registrant is without state authority to handle controlled substances in the state in which the registrant practices. The Controlled Substances Act (“CSA”) provides that obtaining a DEA registration is conditional on holding a state license to handle controlled substances. *See* 21 U.S.C. 802(21) (2006) (defining “practitioner” as “a physician * * * 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. 823(f) (2006) (“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”). The DEA, therefore, has consistently held that the CSA requires the DEA to revoke the registration of a practitioner who no longer possesses a state license to handle controlled substances. *See* 21 U.S.C. 824(a)(3) (2006) (stating “a registration may be suspended or revoked by the Attorney General upon a finding that the registrant has had his State license or registration suspended, revoked or denied by competent State authority”); *Beverly P. Edwards, M.D.*, 75 FR 49,991 (DEA 2010); *Joseph Baumstarck, M.D.*, 74 FR 17,525 (DEA 2009).

In this case, the Government has provided adequate documentation that the Respondent’s New Mexico medical license was suspended on July 6, 2012, and further revoked on December 17, 2012. *See* Government’s Motion at Exh. B and C. Furthermore, although the Respondent failed to file a response to the Government’s Motion for Summary Disposition, the Respondent admitted in his January 16, 2013 Request for Hearing that “Dr. Jain does not have authority to practice medicine or handle controlled substances in the State of New Mexico.” [Respondent’s Request for Hearing at 1]. Although the Respondent is seeking review of the New Mexico Medical Board’s decision to revoke his medical license,⁴ this is not a sufficient reason to stay these proceedings. The law is clear that when the Respondent is

without state authority to practice medicine, his DEA registration must be revoked. *See* 21 U.S.C. 824(a)(3); *Edwards*, 75 FR 49,991; *Baumstarck*, 74 FR 17,525.

Although it is not disputed that the Respondent currently lacks state authority to practice medicine and handle controlled substances, the Respondent contends that his continued DEA registration is within the public interest. *See* Respondent’s Request for Hearing at 2–4. Respondent argues that even though his state medical license has been revoked, a decision which he is appealing, he is entitled to a hearing in this matter because there are “genuine issues of material fact” that will be introduced through expert testimony, records, and other documents that demonstrate “that given the totality of the facts and circumstances in the record, revoking his DEA COR registration would not be appropriate or justified.” [*Id.* at 3]. Additionally, the Respondent contends that he has over 40 years of experience in the medical field and “has never been the subject of any allegations that his medical practice is inconsistent with the public interest.” [*Id.*]. The Respondent also asserts that he has no conviction record and has always complied with federal and state laws relating to controlled substances. [*Id.* at 3–4]. Lastly, the Respondent asserts that the allegations in the Order to Show Cause are “in dispute and not accurate.” [*Id.* at 4]. Moreover, the Respondent argues that his expert witness will be able to prove that the Respondent’s practices were for a legitimate medical purpose and “within acceptable limits of the recognized standard of care in the field of pain management.” [*Id.*].

While the Respondent may have raised genuine disputes of fact concerning the allegations in the Government’s Order to Show Cause, those disputes are immaterial in light of the Respondent’s current lack of state registration. Indeed, the CSA and Agency precedent make clear that as a prerequisite to DEA registration the Respondent must have state authority to handle controlled substances, and that without such authority all other issues before this forum are moot. *See* 21 U.S.C. 802(21); 21 U.S.C. 823(f); *Joseph Baumstarck, M.D.*, 74 FR at 17,527 (DEA 2009). Thus, because there is no dispute that the Respondent lacks state authority to practice medicine and handle controlled substances, the Respondent’s registration must be revoked.

Moreover, because there is no genuine dispute as to any material fact and substantial evidence shows that

Respondent is presently without state authority to practice medicine and handle controlled substances in New Mexico, summary disposition is warranted. It is well settled that when there is no question of material fact involved, there is no need for a plenary administrative hearing and that summary disposition is appropriate. *See Layfe Robert Anthony, M.D.*, 67 FR 35,582 (DEA 2002); *Michael G. Dolin, M.D.*, 65 FR 5,661 (DEA 2000); *Jesus R. Juarez, M.D.*, 62 FR 14,945 (DEA 1997). Accordingly, both the plain language of the CSA and Agency interpretive precedent dictate that summary disposition is appropriate and the Respondent’s DEA registration must be revoked because Respondent is without state authority to practice medicine and handle controlled substances.

B. Respondent Is Entitled To Reapply for Registration With the DEA

Any person who is required to register with the DEA may apply for registration at any time. 21 CFR 1301.13(a) (2012) (“Any person who is required and who is not registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person”).

The Respondent is permitted to reapply for a Certificate of Registration with the DEA at any time in the future. 21 CFR 1301.13(a). However, the Respondent will not be permitted to engage in activity for which a registration is required until his application is granted by the DEA. *Id.*

III. Conclusion, Order, and Recommendation

Consequently, there is no genuine dispute of material fact regarding the Respondent’s lack of state authority to practice medicine and handle controlled substances. Thus, summary disposition for the Government is appropriate. It is well settled that when there is no question of material fact involved, there is no need for a plenary, administrative hearing. *See Dolin*, 65 FR 5,661. Here, there is no genuine dispute that the Respondent currently lacks state authority to practice medicine and to handle controlled substances in New Mexico.

Accordingly, I hereby *Deny* the Respondent’s Motion for a Stay; further I

Grant the Government’s Motion for Summary Disposition.

I also forward this case to the Deputy Administrator for final disposition. I

⁴In Respondent’s January 16, 2012 Request for Hearing, he contends that he has a pending request before the New Mexico Medical Board to reopen his case and that this request “will be heard and ruled on by the Board within 60 days of the date of this letter.” [Respondent’s Request for Hearing at 2].

recommend that the Respondent's DEA Certificate of Registration, Number BJ5128067, be revoked.⁵

Dated: February 12, 2013.
Gail A. Randall,
Administrative Law Judge.

[FR Doc. 2013-07195 Filed 3-27-13; 8:45 am]
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Stepan Company

This is notice that on February 6, 2013, Stepan Company, Natural Products Department, 100 W. Hunter Avenue, Maywood, New Jersey 07607, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of Coca Leaves (9040), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance to manufacture bulk controlled substance for distribution to its customer.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007).

As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745, all applicants for registration to import a basic class of any controlled substance in schedules 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.

Dated: March 19, 2013.

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

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⁵ The sole basis of my recommendation is the loss of Respondent's state licensure. I make no findings or conclusions concerning the other allegations asserted in the Order to Show Cause.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; SA INTL GMBH C/O., Sigma Aldrich Co. LLC

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on February 1, 2013, SA INTL GMBH C/O., Sigma Aldrich Co. LLC., 3500 Dekalb Street, St. Louis, Missouri 63118, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
Aminorex (1585)	I
Gamma Hydroxybutyric Acid (2010)	I
Methaqualone (2565)	I
Alpha-ethyltryptamine (7249)	I
lbogaine (7260)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
3,4-Methylenedioxyamphetamine (7400)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (MDMA) (7405)	I
4-Methoxyamphetamine (7411)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470)	I
N-Benzylpiperazine (7493)	I
Heroin (9200)	I
Normorphine (9313)	I
Etonitazene (9624)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Nabilone (7379)	II
Phencyclidine (7471)	II

Drug	Schedule
Cocaine (9041)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaine (9333)	II
Opium, powdered (9639)	II
Levo-alphaacetylmethadol (9648) ..	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis.

In reference to drug codes 7360 and 7370, the company plans to import a synthetic cannabidiol and a synthetic Tetrahydrocannabinol. No other activity for this drug code is authorized for this registration.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417(2007).

In regard to the non-narcotic raw material, any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), 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 written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than April 29, 2013.

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 basic classes of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of