Outlet, 64 FR 14269 (1999). *See also,* Henry J. Schwartz, Jr., M.D., 54 FR 16422 (1989).

The Deputy Administrator finds factors one, two, three, four and five relevant to the pending application for registration.

As to factors one through four, RAM's owners and operators have a history of distributing List I chemical products which were then diverted while the company operated as AWD and an employee with a close relationship to the Khorchids, sold listed products to an undercover officer believing they would be used to manufacture methamphetamine. That employee was subsequently convicted of a state crime involving controlled substances. As a result of these activities, Mr. Khorchid surrendered AWD's registration and incorporated RAM only a few months later. That company now seeks to sell listed products to the gray market, including those manufactured by PDK Labs, just as it did when operating solely under the AWD name. These four factors weigh against granting the pending application.

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor also weighs heavily against granting the application. Unlawful methamphetamine use is a growing public health and safety concern throughout the United States, including Texas. Ephedrine and pseudoephedrine are precursor products needed to manufacture methamphetamine and operators of illicit methamphetamine laboratories regularly acquire the precursor products needed to manufacture the drug from convenience stores and gas stations which, in prior DEA decisions, have been identified as constituting the gray market for List I chemical products. It is apparent that Mr. Khorchid intends on again becoming a participant in this market, just as he did when registered under AWD's identity.

While there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found these establishments serve as sources for the diversion of large amounts of listed chemical products. *See, e.g.,* ANM Wholesale, 69 FR 11652 (2004); Xtreme Enterprises, Inc., *supra,* 67 FR 76195; Sinbad Distributing, 67 FR 10232 (2002); K.V.M. Enterprises, 67 FR 70968 (2202).

The Deputy Administrator has previously found that many considerations weighed heavily against registering a distributor of list I chemicals because, ''[v]irtually all of the Respondent's customers, consisting of gas station and convenience stores, are considered part of the gray market, in which large mounts of listed chemicals are diverted to the illicit manufacture of amphetamine and methamphetamine.'' Xtreme Enterprises, Inc., *supra,* 67 FR at 76197. As in Xtreme Enterprises, Inc., Mr. Khorchid's personal lack of a criminal record, his discharge of former-AWD employee John Doe and purported intent to comply with the law and regulations, are far outweighed by his intent to sell pseudoephedrine products almost exclusively to the gray market.

The Deputy Administrator is particularly troubled by AWD's history, indicating its owners and operators, now principals of RAM, cannot be trusted to handle the responsibilities of a registrant. Further, RAM's continued use of AWD's name in a d/b/a capacity, raises further questions about RAM's customer base and the risk that its products will be sold to previous customers of AWD and then diverted to illegal purposes.

Based on the foregoing, the Deputy Administrator concludes that granting the pending application would be inconsistent with the public interest.

Accordingly, the Deputy administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders the pending application for DEA Certificate of Registration, submitted by RAM, Inc. d/b/a American Wholesale Distribution Corporation, be, and it hereby is, denied. This order is effective April 8, 2005.

Dated: January 14, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–4565 Filed 3–8–05; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mario Avello, M.D.; Revocation of Registration

On May 17, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Mario Avello, M.D. (Dr. Avello) of Coral Gables, Florida. Dr. Avello was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AA0105747, as a practitioner, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for reason that his continued registration would be inconsistent with the public interest. Dr. Avello was further notified that his DEA registration was immediately suspended as an imminent danger to the public health and safety pursuant to 21 U.S.C. 824(d).

The Order to Show Cause and Immediate Suspension alleged in sum, that Dr. Avello was engaged in illegally prescribing controlled substances as part of a scheme in which controlled substances were dispensed by pharmacies, based on Internet prescriptions issued by Dr. Avello and associated physicians, based solely on their review on Internet questionnaires and without personal contact, examination or bona fide physician/patient relationships. Such prescriptions were not issued ''in the usual course of professional treatment'' and violated 21 CFR 1306.04 and 21 U.S.C. 841(a). This action was part of a nationwide enforcement operation by DEA titled Operation Pharmnet, which targeted online suppliers of prescription drugs, including owners, operators, pharmacists and doctors, who have illegally and unethically been marketing controlled substances via the Internet.

According to the investigative file, the Order to Show Cause and Immediate Suspension of Registration was personally served upon Dr. Avello by DEA Diversion Investigators on May 20, 2004. More than thirty days have passed since the Order to Show Cause and Immediate Suspension of Registration was served and DEA has not received a request for hearing or any other reply from Dr. Avello or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause and Immediate Suspension of Registration to Dr. Avello, and (2) no request for hearing having been received, concludes that Dr. Avello is deemed to have waived his hearing right. *See* David W. Linder, 67 FR 12579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds Dr. Avello is currently registered with DEA as a practitioner under DEA Registration, AA0105747 for Schedule II through V Controlled Substances. That registration expires on June 30, 2006. His registered address is 363 Aragon

Avenue, Apartment 413, Coral Gables, Florida 33134. However, information obtained from the Florida Power & Light Company indicates that someone other than Dr. Avello has been paying the utility bills for that apartment since September 2003, and that Dr. Avello has been paying the utility bills for another apartment in the same building, Apartment No. 711, since March 2003.

In September 2003, DEA investigators executed a federal search warrant on a pharmacy in Iowa and seized multiple prescriptions that had been issued by Dr. Avello pursuant to his relationship with Pharmacon International, L.L.C. (Pharmacon), an Internet drug company which was doing business on *http://WWW.Buymeds.com* and other affiliated Web sites.

Customers would access a Pharmacon Web site and complete on-line questionnaires asking some medical history questions and soliciting information as to what drug they were seeking and the method of payment. The questionnaire would be electronically forwarded to Dr. Avello and, based on the answers to the questionnaire, he would issue prescriptions for the desired controlled substances. The primary drug prescribed pursuant to this scheme was hydrocodone, a Schedule III controlled substance.

Dr. Avello did not see the customers and had no prior doctor-patient relationships with them. He did not conduct physical examinations, nor did he create or maintain patient records. The only information usually reviewed prior to issuing prescriptions was the customer's questionnaire and Dr. Avello did not consult with the primary care physicians.

The Iowa Board of Pharmacy contacted over 400 listed customers of Buymeds.com to verify purported prescriptions. Approximately half of these people advised they never had any contact with the prescribing physician or filling pharmacy. They stated their only contact with Buymeds.com had been through the Internet Web site, where they filled out the brief questionnaire, indicated the form of payment and requested their drugs of choice. None of the individual customers had any personal contact with the prescribing physicians and many prescriptions had been issued to minors.

Approximately 40 individuals were contacted by the Iowa Board who had received controlled substances from Buymeds.com that had been prescribed by Dr. Avello. Every customer stated that before receiving their controlled substances they had no personal contact with Dr. Avello, except by e-mail.

Dr. Avello, who entered into a ''Professional Services Agreement'' with Pharmacon on May 5, 2003, received payment for each questionnaire reviewed and he admitted reviewing approximately 100 to 200 requests for prescriptions per day. Dr. Avello's son, Alexis M. Avello, was an officer of Pharmacon and a signator on the company's contract with Dr. Avello.

The Controlled Substances Act (CSA) establishes a ''closed system'' of distribution that regulates the movement of controlled substance prescription medications from importation or manufacture through their delivery to the ultimate user patient via the dispensing, administering or prescribing, pursuant to the lawful order of a practitioner. The regulations implementing the CSA explicitly describe the parameters of a lawful prescription as follows: ''A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

Prescriptions issued not in the ''usual course of professional treatment'' are not ''prescriptions'' for purposes of the CSA and individuals issuing and filling such purported prescriptions are subject to the penalties for violating the CSA's controlled substances provisions.

In *United States* v. *Moore,* 423 U.S. 122 (1975), the Supreme Court held that, ''Implicit in the registration of a physician is the understanding that he is authorized only to act 'as a physician'.'' *Id.,* at 141. In Moore the court implicitly approved a jury instruction that acting ''as a physician'' is acting ''in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.'' *Id.,* at 138–139; *see, United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

Responsible professional organizations have issued guidance in this area. The American Medical Association's guidance for physicians on the appropriate use of the Internet in prescribing medication (H–120.949 Guidance for Physicians on Internet Prescribing) states:

> ''Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall:
>
> i. obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;
>
> ii. have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);
>
> iii. as appropriate, follow up with the patient to assess the therapeutic outcome;
>
> iv. maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and
>
> v. include the electronic prescription information as part of the patient medical record.''

In April 2000, the Federation of State Medical Boards adopted Model Guidelines for the Appropriate use of the Internet in Medical Practice, which state, in pertinent part, that:

> ''Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptance standard of care.''

The CSA regulations establish certain responsibilities not only on individual practitioners who issue prescriptions for controlled substances, but also on pharmacists who fill them. A pharmacist's ''corresponding responsibility'' regarding the proper dispensing of controlled substances is explicitly described in 21 CFR 1306.04(a). It provides:

> ''A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.''

In an April 21, 2001, policy statement, entitled *Dispensing and Purchasing Controlled Substances Over the Internet,* 66 FR 21,181 (2001), DEA delineated certain circumstances in which prescribing over the Internet is unlawful. The policy provides, inter alia, that a controlled substance should not be issued or dispensed unless there was a bona fide doctor/patient relationship. Such a relationship required that the patient has a medical complaint, a medical history be taken, a physical examination performed, and some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed. The policy

statement specifically explained that the completion of ''a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship * * *'' *Id.*, at 21,182–83.

Rogue Internet pharmacies bypass a legitimate doctor-patient relationship, usually by use of a cursory and incomplete online questionnaire or perfunctory telephone ''consult'' with a doctor, who usually has a contractual arrangement with the online pharmacy and is often paid on the basis of prescriptions issued. The Food and Drug Administration (FDA) considers the questionnaire, in lieu of face-to-face interaction, to be a practice that undermines safeguards of direct medical supervision and amounts to substandard medical care. *See* U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (*http://fda.gov/oc/buyonline/default.htm*).

The National Association of Boards of Pharmacy considers internet pharmacies to be suspect if:

> ''They dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional.''

See, National Association of Boards of Pharmacy, VIIPS Program, Most Frequently Asked Questions (*http://www.nabp.net/vipps/consumer/faq.asp).*

Rogue Internet pharmacies often use persons with limited or no knowledge of medications and standard pharmacy practices to fill prescriptions, do not advertise the availability of pharmacists for medication consultation, and focus on select medications, usually lifestyle, obesity and pain medications. Rogue Internet pharmacies generally do not protect the integrity of original faxed prescriptions by requiring that they be received directly from the prescriber (not the patient) and do not verify the authenticity of suspect prescriptions.

When the established safeguards of an authentic doctor-patient relationship are lacking, controlled substance prescription drugs can not only be misused, but also present potentially serious health risks to patients. Rogue Internet pharmacies facilitate the easy circumvention of legitimate medical practice. The FDA has stated:

> ''We know that adverse events are under-reported and we know from history that tolerating the sale of unproven, fraudulent, or adulterated drugs results in harm to the public health. It is reasonable to expect that the illegal sales of drugs over the Internet and the number of resulting injuries will increase as sales on the Internet grow. Without clear and effective law enforcement, violators will have no reason to stop their illegal practices. Unless we begin to act now, unlawful conduct and the resulting harm to consumers most likely will increase.''

See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs *(http://fda.gov/oc/buyonline/default.htm).*

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal of such registration, if she determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing or conducting research with respect to 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 or safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See* Henry J. Schwartz, Jr., M.D., 54 FR 16422 (1989).

In this case, the Deputy Administrator finds factors two, four and five relevant to a determination of whether Dr. Avello's continued registration remains consistent with the public interest.

With regard to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, there is no evidence in the investigative file that Dr. Avello has been the subject of a state disciplinary proceeding, nor is there evidence demonstrating that his state medical license or state controlled substance authority are currently restricted in any form. Nevertheless, state licensure is a necessary, but not sufficient condition for registration, and therefore, this factor is not dispositive. *See e.g.,* Wesley G. Harline, M.D., 65 FR 5,665–01 (2000); James C. LaJevic, D.M.D., 64 FR 55,962 (1999).

With regard to factors two and four, the Deputy Administrator finds that the primary conduct at issue in this proceeding (*i.e.,* the unlawful prescribing and dispensing of controlled substance prescriptions for use by Internet customers) relates to Dr. Avello's experience in prescribing controlled substances, as well as his compliance with applicable State, Federal, or local laws relating to controlled substances.

A DEA registration authorizes a physician to prescribe or dispense controlled substances only within the usual course of his or her professional practice. For a prescription to have been issued within the course of a practitioner's professional practice, it must have been written for a legitimate medical purpose within the context of a valid physician-patient relationship. *See* Mark Wade, M.D., 69 FR 7018 (2004). Legally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription. *See* Floyd A. Santner, M.D., 55 FR 37581 (1990).

The Deputy Administrator concludes from a review of the record that Dr. Avello did not establish valid physician-patient relationships with the Internet customers to whom he prescribed controlled substances. DEA has previously found that prescriptions issued through pharmacy Internet websites under these circumstances are not considered as having been issued in the usual course of medical practice, in violation of 21 CFR 1306.04 and has revoked DEA registrations of several physicians for participating in Internet prescribing schemes similar to or identical to that of Dr. Avello and Pharmacon. *See,* Marvin L. Gibbs, Jr., M.D., 69 FR 11,658 (2004); Mark Wade, M.D., *supra,* 69 FR 7,018; Ernesto A. Cantu, M.D., 69 FR 7,014–02 (2004); Rick Joe Nelson, M.D., 66 FR 30,752 (2001).

Similarly, DEA has issued orders to show cause and subsequently revoked DEA registrations of pharmacies which have failed to fulfill their corresponding responsibilities in Internet prescribing operations similar to, or identical to that of Dr. Avello and Pharmacon. *See,* EZRX, L.L.C. (EZRX), 69 FR 63,178

(2004); Prescriptionline.com, 69 FR 5,583 (2004).

In the instant case, Dr. Avello and other physicians associated with the Internet scheme, authorized prescriptions for controlled substances without the benefit of face-to-face physician-patient contact, physical exam or medical tests. Beyond occasional phone calls to some customers or their family members, there is no information in the investigative file demonstrating that Dr. Avello and other issuing physicians associated with Pharmacon even took time to corroborate response to questionnaires submitted by the customers. Here, it is clear the issuance of controlled substance prescriptions to persons whom Dr. Avello had not established a valid physician-patient relationship is a radical departure from the normal course of professional practice and he knowingly participated in this scheme.

With regard to factor three, Dr. Avello's conviction record under Federal or State laws relating to the dispensing of controlled substances, the record does not reflect that he has been convicted of a crime related to controlled substances.

Regarding factor five, such other conduct which may threaten the public health or safety, the Deputy Administrator finds this factor relevant to Dr. Avello's continued prescribing to Internet customers after issuance of policy statements designed to assist licensed practitioners and pharmacists in the proper prescribing and dispensing of dangerous controlled drugs.

The Deputy Administrator has previously expressed her deep concern about the increased risk of diversion which accompanies Internet controlled substance transactions. Given the nascent practice of cyber-distribution of controlled drugs to faceless individuals, where interaction between individuals is limited to information on a computer screen or credit card, it is virtually impossible to insure that these highly addictive, and sometimes dangerous products will reach the intended recipient, and if so, whether the person purchasing these products has an actual need for them. The ramifications of obtaining dangerous and highly addictive drugs with the ease of logging on to a computer and the use of a credit card are disturbing and immense, particularly when one considers the growing problem of the abuse of prescription drugs in the United States. *See,* EZRX, *supra,* 69 FR at 63181; Mark Wade, M.D., *supra,* 69 FR 7018.

The Deputy Administrator has also previously found that in a 2001 report, the National Clearinghouse for Alcohol and Drug Information estimated that 4 million Americans ages 12 and older had acknowledged misusing prescription drugs. That accounts for 2% to 4% of the population—a rate of abuse that has quadrupled since 1980. Prescription drug abuse—typically of painkillers, sedatives and mood altering drugs—accounts for one-third of all illicit drug use in the United States. *See* EZRX, *supra*, 69 FR at 63181–82, Mark Wade, M.D., *supra*, 679 FR 7018.

The Deputy Administrator finds that with respect to Internet transactions involving controlled substances, the horrific untold stories of drug abuse, addiction and treatment are the unintended, but foreseeable consequence of providing highly addictive drugs to the public without oversight. The closed system of distribution, brought about by the enactment of the Controlled Substances Act, is completely compromised when individuals can easily acquire controlled substances without regard to age or health status. Such lack of oversight describes Dr. Avello's practice of issuing prescriptions for controlled substances to indistinct Internet customers which are then filled by pharmacies participating in the scheme. Such conduct contributes to the abuse of controlled substances by Dr. Avello and Pharmacon's customers and is relevant under factor five, further supporting revocation of his DEA Certificate of Registration.

Motivated purely by profit and in pursuit of financial gain, Dr. Avello has demonstrated a cavalier disregard for controlled substance laws and regulations and a disturbing indifference to the health and safety of individuals who purchased dangerous drugs through the Internet. Such demonstrated lack of character and adherence to the responsibilities inherent in a DEA registration show in no uncertain terms that Dr. Avello's continued registration with DEA would be inconsistent with the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AA0105747, issued to Mario Avello, M.D., be, and is hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal of such registration be, and they hereby are denied. This order is effective April 8, 2005.

Dated: January 14, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–4563 Filed 3–8–05; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Samuel Lee Steel, M.D.; Revocation of Registration

On August 20, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Samuel Lee Steel, M.D. (Dr. Steel) who was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration BS5024865, pursuant to 21 U.S.C. 824(a)(3) and deny any pending applications under 21 U.S.C. 823(f), on the ground that he lacked state authority to handle controlled substances in the State of California. The Order to Show Cause also notified Dr. Steel that should no request for a hearing be filed with 30 days, his hearing right would be deemed waived.

The order to Show Cause was sent by certified mail to Dr. Steel at his registered address of 1150 North Canyon Drive, Palm Springs, California 92263. According to the return receipt of the Order, it was accepted on Dr. Steel's behalf on September 1, 2004. DEA has not received a request for hearing or any other reply from Dr. Steel or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause to the registrant's address of record and (2) no request for hearing having been received, concludes that Dr. Steel is deemed to have waived his hearing right. *See* David W. Linder, 67 FR 12579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Dr. Steel is currently registered with DEA as a practitioner authorized to handle controlled substances in Schedules II through V under Certificate of Registration BS5024865, expiring on February 29, 2005. According to information in the investigative file, following an Interim Order of Suspension, on April 1, 2004, the Medical Board of California (Board)