

remedy, the public interest and bonding. On January 27, 2003, the Commission issued a notice indicating that it had determined that there is a violation of section 337 of the Tariff Act of 1930, as amended, and had issued a limited exclusion order prohibiting the importation of the infringing sortation systems, parts and components thereof, manufactured abroad by Vanderlande. The Federal Circuit affirmed the Commission's determination on May 3, 2004. *See Vanderlande Indus. v. Int'l Trade Comm'n*, 366 F.3d 1311 (Fed. Cir. 2004).

On February 2, 2005, Vanderlande and complainants filed a joint petition to rescind the remedial order under Commission Rule 210.76(a)(1) on the basis of a settlement agreement between the parties. The parties asserted that their settlement agreement constituted "changed conditions of fact or law" sufficient to justify rescission of the order under Commission Rule 210.76(a)(1), 19 CFR 210.76(a)(1). The IA filed a response in support of the motion on February 14, 2005.

Having reviewed the parties' submissions, the Commission has determined that the settlement agreement satisfies the requirement of Commission Rule 210.76(a)(1), 19 CFR 210.76(a)(1), that there be changed conditions of fact or law. The Commission therefore has issued an order rescinding the limited exclusion order previously issued in this investigation.

This action is taken under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and § 210.76(a)(1) of the Commission's Rules of Practice and Procedure (19 CFR 210.76(a)(1)).

Issued: March 3, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

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DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[Docket No. ATF 17N; ATF O 1150.13]

Delegation Order—Designation of Acting Supervisory Officials

1. *Purpose.* The purpose of this delegation order is to grant supervisors authority to designate acting supervisory officials of the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF).

2. *Cancellations.* ATF O 1100.9A, Delegation Order—Designation of Acting Supervisory Officials dated October 7, 1980 and ATF F 1100.1, Temporary Assignment Designation.

3. *Authorities.* Pursuant to authorities vested in the Director, ATF, by Title 6 U.S.C. 531 and 28 CFR O.130-0.133.

4. *Designations.*

a. An official e-mail notification is required for supervisors to designate a subordinate employee to act in the event of their absence or in a subordinate supervisory position in which such position becomes vacant. At a minimum, the official e-mail notification must be sent to individuals who report directly to the supervisor; the individual to whom the supervisor reports; and any other individual(s) who need to be advised. An official e-mail notification is not required if there exists a document or order that designates a temporary acting official.

b. In the event of an emergency, ATF O 1100.59G, Delegation Order—Emergency Order of Succession and Delegation of Authority, designates the order of succession for Acting Director to ensure the continuity of Bureau functions. Under these circumstances no e-mail notification is required.

5. *Retention Requirements.* Acting designations must be retained in accordance with ATF O 1345.1, Records Management Program and Records Control Schedule 101, item 2 (Headquarters) and ATF Records Control Schedule 201, item 1 (Field).

6. *Redelegation.* The authority to designate acting supervisory officials is delegated to all Bureau personnel in supervisory positions and may not be redelegated.

7. *Questions.* Questions regarding this delegation order may be addressed to the Chief, Document Services Branch at (202) 927-8930.

Dated: February 18, 2005.

Carl J. Truscott,

Director.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

RAM, INC. d/b/a American Wholesale Distribution Corp.; Denial of Registration

On July 23, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to RAM Inc., d/b/a American Wholesale Distribution

Corporation (RAM), proposing to deny its June 5, 2003, application for DEA Certificate of Registration as a distributor of List I chemicals. The Order to Show Cause alleged that granting RAM's application would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h). The order also notified RAM that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to RAM at its proposed registered location at 3300 Pleasant Valley Lane, Suite C, Arlington, Texas 76015. It was received on August 2, 2004, and DEA has not received a request for a hearing or any other reply from RAM or anyone purporting to represent the company in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days have passed since delivery of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that RAM has waived its hearing right. *See* *Aqui Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53(c) and (d) and 1316.67. The Deputy Administrator finds as follows.

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1300.02(a). Pseudoephedrine and ephedrine are List I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. As noted in previous DEA orders, methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a persistent and growing problem in the United States. *See e.g.*, *Direct Wholesale*, 69 FR 11654 (2004); *Branex, Inc.*, 69 FR 8682 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.*, 67 FR 9997 (2002); *Denver Wholesale*, 67 FR 99986 (2002).

The Deputy Administrator's review of the investigative file reveals that RAM's owner and only officer is Mr. Mohamad Khorchid. On or about June 5, 2003, an application was submitted by Mr. Khorchid on behalf of RAM, seeking registration to distribute ephedrine and pseudoephedrine List I chemical products. It identified the applicant as "RAM INC American Wholesale Dist. Co."

Prior to RAM's February 7, 2003, incorporation, Mr. Khorchid and his wife owned and operated American

Wholesale Distribution Corporation (AWD), also of Arlington, Texas, which was registered as a distributor of List I chemical products on April 15, 1999, under DEA Certificate of Registration 004169ASY.

During AWD's 1999 pre-registration inspection, DEA investigators discussed requirements for recordkeeping and suspicious order reporting with Mr. and Mrs. Khorchid and provided written information regarding combination ephedrine and pseudoephedrine drug products used in illicitly manufacturing methamphetamine. A juvenile employee of AWD [John Doe] was present at this meeting and the three were advised it was illegal to sell List I chemical products knowing they would be used to manufacture illegal drugs. During this conversation, Mr. Khorchid advised investigators that AWD sold sundry items to area convenience stores and that List I chemical products would make up about 15% of the company's total sales.

During a July 2001 regulatory investigation, Mr. Khorchid advised DEA investigators that 99% of AWD's customers were convenience stores and that List I chemical products made up about 10% of its sales. An inventory conducted as a part of that investigation showed AWD maintained a substantial inventory of ephedrine and pseudoephedrine products manufactured or distributed by two companies, Lannett Company, Inc. (Lannett) and PDK Labs, Inc. (PDK). The inventory included several Max Brand products, which are manufactured by PDK.

DEA is aware that Lannett and PDK's ephedrine and pseudoephedrine products have been discovered by law enforcement agencies at clandestine methamphetamine laboratories and other illicit sites throughout the country. *See Indace, Inc, c/o Seegott, Inc; Malladi, Inc., (Indace), 69 FR 67951 (2004) (Suspension of Shipment of ephedrine hydrochloride being imported for distribution to PDK Labs, Inc.).* Further, during this period, no other ephedrine and pseudoephedrine manufacturers had as much diversion of their products as Lannett and PDK. DEA has previously found that PDK's Max Brand products are the precursors "predominantly encountered and seized at clandestine methamphetamine laboratories" and that "[c]onvenience stores are also the primary source for the purchase of the Max Brand products, which are the preferred brand for use by illicit methamphetamine producers, and users." *See Express Wholesale, 69 FR 62086, 62087, 62089 (2004).*

In April 2002, DEA investigators received information that AWD employee John Doe, who had a close personal relationship with the Khorchids, was falsifying company invoices to account for unlawful sales of pseudoephedrine. On June 11, 2002, an undercover operation was conducted which resulted in Doe selling a case of Action Brand PSE and four dozen bottles of Max Brand PSE to an undercover agent for about \$1600.00, believing the products would be used to manufacture methamphetamine.

In July 2002, Diversion Investigators obtained Mr. Khorchid's consent to perform an administrative inspection of AWD. A review of the company's sales records from April 2001 through July 2002 showed AWD sold large amounts of Lannett and PDK pseudoephedrine and ephedrine products to numerous area convenience stores. In many instances, the purchases of these products were well in excess of any potential legitimate demand. *See Branex, Inc., supra, 69 FR at 8693 (expert testimony on the legitimacy of selling listed chemical products in the "gray market"); Xtreme Enterprises, Inc., 67 FR 76195, 76197 (2002) (same); Value Wholesale, 69 FR 58548 (2004); see also Indace, supra, 69 FR at 67962 and cases cited therein.*

On July 30, 2002, investigators informed Mr. Khorchid about the investigation involving John Doe and requested surrender of the company's DEA registration, which was done on October 1, 2002. The employee was subsequently prosecuted in state juvenile court and pled guilty to conspiring to manufacture a controlled substance (methamphetamine).

During DEA's pre-registration investigation into RAM's pending application, Mr. Khorchid advised investigators that the new company's prospective customers would continue to be convenience stores and he also intended to sell PDK manufactured pseudoephedrine and ephedrine products.

DEA is aware that small illicit laboratories operate with listed chemical products often procured, legally or illegally, from non-traditional retailers of over-the-counter drug products, such as gas stations and small retail markets. Some retailers acquire product from multiple distributors to mask their acquisition of large amounts of listed chemicals. In addition, some individuals utilize sham corporations of fraudulent records to establish a commercial identity in order to acquire listed chemicals.

DEA knows by experience that there exists a gray market in which certain

high strength, high quantity pseudoephedrine and ephedrine products are distributed only to convenience stores and gas stations, from where they have a high incidence of diversion. These gray market products are not sold in large discount stores, retail pharmacies or grocery stores, where sales of therapeutic over-the-counter drugs predominate.

DEA also knows from industry data, market studies and statistical analysis that over 90% of over-the-counter drug remedies are sold in drug stores, supermarket chains and "big box" discount retailers. Less than one percent of cough and cold remedies are sold in gas stations or convenience stores. Studies have indicated that most convenience stores could not be expected to sell more than \$20.00 to \$40.00 worth of products containing pseudoephedrine per month. The expected sales of ephedrine products are known to be even smaller. Furthermore, convenience stores handling gray market products often order more product than what is required for the legitimate market and obtain chemical products from multiple distributors. *See CWK Enterprises, Inc., 69 FR 69400 (2004); Prachi Enterprises, Inc., 69 FR 69407 (2004); Volusia Wholesale, 69 FR 69409; Branex, Inc., supra, 69 FR at 8693.*

Pursuant to 21 U.S.C. 823(h), the Deputy Administrator may deny an application for a Certificate of Registration if she determines that granting the registration would be inconsistent with the public interest. Section 823(h) requires that the following factors be considered in determining the public interest:

- (1) Maintenance of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) Compliance with applicable Federal, State and local law;
- (3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) Any past experience of the applicant in the manufacture and distribution of chemicals; and
- (5) Such other factors as are relevant to and consistent with the public health and safety.

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, 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, e.g., Energy*

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 (2002).

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.

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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