DEA approval to modify here registered address. She also indicated that she had been invited to resume work as a physician at CCPMC and it was alleged that she had continued her prescribing practices, even after becoming aware of DEA's investigation into those practices.

On July 3, 2001, counsel for Dr. Bordeaux requested a hearing and following prehearing procedures, Presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) scheduled the hearing to begin on July 16, 2002. On July 10, 2002, counsel for Dr. Bordeaux filed a Motion to Defer Hearing as a result of her indictment by a Federal grant jury on charges stemming from the conduct alleged in the Order to Show Cause/Immediate Suspension of Registration. That motion was granted on July 10, 2002.

On February 27, 2004, counsel for the Government filed a Motion for Summary Judgment. It alleged that on February 10, 2003, Dr. Bordeaux had been convicted in United States District Court for the District of South Carolina, of Conspiracy to Unlawfully Distribute Controlled Substances, in violation of 21 U.S.C. 846. Further, the motion alleged that March 10, 2003, the State Board of Medical Examiners of South Carolina (Medical Board) issued an Order of Temporary Suspension of Dr. Bordeaux's license to practice medicine in South Carolina and that she was no longer authorized to handle controlled substances in the State in which she maintained her DEA registration.

The Government attached to its motion an affidavit from a Medical Board investigator documenting the Federal conviction, a copy of the Order of Temporary Suspension and a February 20, 2004, letter from the Medical Board, indicating that as of that date, Dr. Bordeaux's medical license was still suspended. While given the opportunity, Dr. Bordeaux did not file a response to the Government's motion.

On May 4, 2004, Judge Bittner issued the Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Bittner granted the Government's Motion for Summary Judgment, finding Dr. Bordeaux lacked authorization handle controlled substances in South Carolina, the jurisdiction in which she is registered with DEA.

In granting the Government's motion, Judge Bittner further recommended that Dr. Bordeaux's DEA registration be revoked and that any pending applications for modification or renewal be denied. No exceptions to the Opinion and Recommended Decision were filed.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Adminstrator adopts, in full, the Opinion and Recommended Decision of the Administrative Law Judge.

The Deputy Administrator finds that Dr. Bordeaux currently possesses DEA Certificate of Registration BB3869370 and is registered to handle controlled substances in the State of South Carolina. The Deputy Administrator further finds that in response to her Federal conviction, on March 10, 2003, the State Board issued an Order of Temporary Suspension immediately suspending Dr. Bordeaux's license to practice medicine in South Carolina. There is no evidence before the Deputy Administrator that the State Board's Order has been lifted, stayed or modified. Therefore, the Deputy Administrator finds that Dr. Bordeaux is currently not licensed to practice medicine in South Carolina and as a result, it is reasonable to infer she is also without authorization to handle controlled substances in that State.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without State authority to handle controlled substances in the State in which she conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See Stephen J. Graham, M.D.,* 69 FR 11661 (2004); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993); *Bobby Watts, M.D.,* 53 FR 11919 (1988). Revocation is also appropriate when a State license has been suspended, but with the possibility of future reinstatement. *See Alton E. Ingram, Jr., M.D.,* 69 FR 22562 (2004); *Anne Lazar Thorn, M.D.,* 62 FR 847 (1997).

Here, it is clear Dr. Bordeaux is not currently licensed to handle controlled substances in South Carolina, where she is registered with DEA. Therefore, she is not entitled to maintain that registration. Because Dr. Bordeaux is not entitled to a DEA registration in South Carolina due to lack of State authorization to handle controlled substances, the Deputy Administrator concludes it is unnecessary to address whether Dr. Bordeaux's registration should be revoked based upon the remaining public interest grounds asserted in the Order to Show Cause/ Immediate Suspension of Registration. *See Fereida Walker-Graham, M.D.,* 68 FR 24761 (2003); *Nathaniel-Aikens-Afful, M.D.,* 62 FR 16871 (1997); *Sam F. Moore, D.V.M.,* 58 FR 14428 (1993).

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, BB3869370, issued to Deborah Bordeaux, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–26306 Filed 11–26–04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

CWK Enterprises, Inc.; 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 CWK Enterprises, Inc. (CWK) proposing to deny its March 1, 2003, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting CWK'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 CWK that should not 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 CWK at its proposed registered location at 3065 McCall Drive, Suite 10, Atlanta, Georgia 30224. It was received on August 5, 2004, and DEA has not received a request for a hearing or any other reply from CWK 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 CWK 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 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. As noted in previous DEA final 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 11,654 (2004); *Branex, Inc.,* 69 FR 8,682 (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 on or about March 1, 2003, an application was submitted by the President of CWK, Mr. Charles In Kim, seeking registration to distribute ephedrine and pseudoephedrine list I chemical products. The application originally included phenylpropanolamine, but that listed chemical product was eventually deleted from the request.

In connection with the pending application, an on-site pre-registration investigation was conducted at the proposed premises. Investigators were advised that CWK, which was incorporated in 2001, was a wholesale distributor of general merchandise to convenience stores and gas stations.

CWK was proposing to sell Mini-Thins and traditional single entity and combination pseudoephedrine products. Investigators noted that CWK had no products list, but the company officer referred to a catalogue produced by a national wholesaler.

At the initial investigation, Mr. Chul Kim, CWK's Vice-President, also failed to provide DEA investigators an updated customer list for listed chemical products. Subsequently, a list of fourteen customers was provided to the investigators. A customer verification revealed that seven of these purported customers either did not know, or did not intend to do listed chemical business with CWK.

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 or fraudulent records to establish a commercial identity in order to acquire listed chemicals.

The illegal production of methamphetamine continues unabated within the DEA Atlanta region. The adjacent State of Tennessee leads the region in the number of clandestine laboratories seized, accounting for approximately 50 percent of the clandestine laboratories seized during the second quarter of 2002. When compared with the third quarter of 2001, the increase in clandestine laboratory seizures is notable. According to later records for the Atlanta region, 360 clandestine laboratories were seized during the third quarter of 2002. Of the 360 laboratories seized during that reporting period, 207 were located in Tennessee, 103 in Georgia, 35 in South Carolina and 15 in North Carolina.

In the State of Georgia, there has been a consistent increase in the number of illicit laboratories and enforcement teams continue to note a trend toward smaller capacity laboratories. This is likely due to the ease of concealment associated with smaller laboratories, which continue to dominate seizures and cleanup responses.

The adjacent State of Tennessee has a substantial methamphetamine abuse problem in the Chattanooga and Eastern Tennessee areas and DEA is aware of a past history of trafficking in precursors in these locations. Distributors or retailers serving the illicit methamphetamine trade observe no borders and trade across State lines. In fact, where precursor laws are stringent, out-of-state distributors often make direct shipments to retailers without observing State requirements.

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. Mini-Thins and other ''two-way'' ephedrine and single entity pseudoephedrine products are prime products in this gray market industry and are rarely found in any retail store serving the traditional therapeutic market.

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. Most 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.

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 four and five relevant to the pending application for registration.

With regard to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant based on CWK's lack of knowledge and experience regarding the laws and regulations governing handling of list I chemical products. In prior DEA decisions, this lack of experience in handling list I chemical products has been a factor in denying pending applications for registration. *See, e.g., Direct Wholesale, supra,* 69 FR 11654; *ANM Wholesale,* 69 FR 11652 (2004);

Xtreme Enterprises, Inc., 67 FR 76195 (2002).

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor weighs heavily against granting the application. Unlawful methamphetamine use is a growing public health and safety concern throughout the United States and Southeast. 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 grey market for list I chemical products. It is apparent that CWK intends on being a participant in this market.

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 Whilesale, supra,* 69 FR 11652; *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 grey market, in which large amounts 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.*, lack of a criminal record and intent to comply with the law and regulations are far outweighed by CWK's lack of experience and the company's intent to sell ephedrine and pseudoephedrine exclusively to the gray market. The Deputy Administrator is further troubled by CWK's providing DEA investigators misleading information, indicating the company cannot be trusted to handle the responsibilities of a registrant.

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 Certification of Registration, previously submitted by CWK Enterprises, Inc., be, and it hereby is, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–26309 Filed 11–26–04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 02–40]

Dan E. Hale, D.O., Denial of Registration

On March 21, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Dan E. Hale, D.O. (Respondent) notifying Respondent of an opportunity to show cause as to why DEA should not deny his application for a DEA Certificate of Registration as a practitioner pursuant to 21 U.S.C. 824(a)(1) and (a)(5) and on grounds that his registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).

The Order to Show Cause alleged in sum that on March 21, 1995, Respondent had been convicted by a jury in United States District Court, Eastern District of Kentucky, of 21 felony counts related to wrongful billing under Medicaid, Medicare and TennCare programs from 1980 to 1993. On June 20, 1995, Respondent surrendered his DEA Certificate of Registration AH7753709 and was subsequently sentenced to a total of 57 months confinement, followed by two years of supervised release.

It was also alleged that on March 18, 1994, the Tennessee Department of Health, Board of Osteopathic Medicine (Board), issued a Notice of Charges alleging, among other things, that Respondent improperly allowed a physician assistant to dispense and prescribe controlled substances without supervision and that in several instances Respondent and the physician assistant, dispensed and prescribed controlled substances in violation of established treatment protocols. On November 8, 1995, he entered into an Agreed Order with the Board, whereby the Board ordered that he surrender his osteopathic medical license and in the event his conviction was upheld on appeal, his license would be automatically revoked. After the conviction was affirmed by the Sixth Circuit Court of Appeal on January 28, 1997, the Board revoked Respondent's medical license. That license was subsequently reinstated on May 25, 2001.

It was further alleged that on January 26, 1996, as a result of Respondent's convictions, the United States Department of Health and Human Services notified him that he was mandatorily excluded from the Medicare program pursuant to 42 U.S.C. 1320a–7(a).

Finally, it was alleged that on June 18, 2001, Respondent materially falsified an application for DEA registration by failing to disclose the voluntary surrender of his previous DEA registration and the revocation of his State osteopathic medical license.

Respondent requested a hearing on the issues raised by the Order to Show Cause and following pre-hearing procedures, a hearing was held in Arlington, Virginia, on January 7 and 8, 2003. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted written proposed findings of fact, conclusions of law, and argument.

On November 26, 2003, Presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (Opinion and Recommended Ruling) in which she concluded that grounds existed to deny Respondent's application for DEA registration and recommended the application be denied. On January 14, 2004, Respondent filed exceptions to Judge Bittner's Opinion and Recommended Ruling and on January 15, 2004, Judge Bittner transmitted the record of these proceedings to the then-Acting Deputy Administrator of DEA.

By his counsel's letter dated March 22, 2004, Respondent asked the Deputy Administrator to consider the impact of recent changes implemented by the State of Tennessee, Bureau of TennCare. Counsel for the Government had no objection and the submission has been considered as a part of the administrative record.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. As set forth below, the Deputy Administrator adopts in whole, the recommended findings of