Accordingly, particularly given Respondent's lack of a plan for a business monitoring system, factor one weights against registration

As to factors two and three, there is no evidence that Mr. Kim has any criminal record or evidence that he violated any laws, which weighs in favor of granting the application.

With regard to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator agrees with Judge Randall that the record demonstrates Mr. Kim lacks experience and knowledge in the distribution of listed chemical products. While he has offered assurances that he now knows the risks involved in handling listed chemical products, the absence of an adequate business plan to minimize the risk to the general public is significant.

In prior DEA decisions, this lack of experience in handling list I chemical products has been a factor in denying pending applications for DEA registration. *See e.g.*, Direct Wholesale, 69 FR 11,654 (2004); ANM Wholesale, 69 FR 11,652 (2004); Xtreme Enterprises, Inc., 67 FR 76,195 (2002). The Deputy Administrator agrees with Judge Randall that this factor weights against granting Respondent's application for registration.

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 specifically in the State of Oklahoma. Pseudoephedrine and ephedrine are the precursor products used to manufacture methamphetamine and users predominantly have acquired the precursor products needed to manufacture the drug from convenience stores and gas stations.

The Deputy Administrator specifically concurs with Judge Randall's finding that Max Brand is the product preferred by illicit methamphetamine manufacturers and users. Also, while Mr. Kim made a belated gesture in agreeing to eliminate Max Brand from his product list, it is only one of multiple precursor products used to manufacture the drug and the same public interest factors apply to other brands as well. As recognized by Judge Randall, ''merely declining to sell the Max Brand product is not enough to outweight the other public interest concerns that must be taken into consideration here.''

While Mr. Kim has not been involved in the manufacturing of methamphetamine, the majority of his proposed customers operate convenience stores and gas stations. As noted by Judge Randall, 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.'' Extreme Enterprises, Inc., supra, 67 FR at 76,197. As in Xtreme Enterprises, Inc., Mr. Kim's lack of a criminal record, compliance with the law and a willingness to upgrade physical security are far outweighed by his lack of experience and his intent to sell ephedrine almost exclusively in the gray market. Id.

The Deputy Administrator additionally takes notice that after the hearing on this matter concluded, Oklahoma enacted House Bill 2176, titled the ''Oklahoma Methamphetamine Reduction Act of 2004.'' Under this statute, which was signed on and made effective as of April 6, 2004, among its provisions, the sale of pseudoephedrine tables is now restricted to licensed pharmacies. Accordingly, Respondent's proposed base of Oklahoma customers in no longer legally viable.

Among the listed chemical products Respondent intends to distribute is phenylpropanolamine. As did Judge Randall, the Deputy Administrator also finds factor five relevant to the request to distribute phenylpropanolamine and apparent lack of safety associated with the use of that product. DEA has previously determined that an applicant's request to distribute phenylpropanolamine constitutes a ground under factor five for denial of an application for registration. *See* ANM Wholesale, 69 FR 11,652 (2004); William E. ''Bill'' Smith d/b/a/ B & B Wholesale, 69 FR 22,559 (2004); Shani Distributors, 68 FR 62,324 (2003).

Based on the foregoing, the Deputy Administrator concludes that granting the pending application of Respondent would be inconsistent with the public interest. As discussed by Judge Randall, DEA is justified in registering only those applicants who grasp the severity of the problem and understand and can implement controls to stop diversion of listed chemical products. Notwithstanding the loss of his customer base as a result of state legislative action, the record here falls woefully short of establishing that Mr. Kim has the requisite level of understanding, ability or willingness to establish and maintain business controls and procedures adequate to prevent diversion of listed chemical products.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for a DEA Certificate of Registration, previously submitted by Express Wholesale be, and it hereby is, denied. This order effective November 22, 2004.

Dated: October 5, 2004

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–23707 Filed 10–21–04; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

J & S Distributors; Denial of Application

On August 11, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to J & S Distributors (J & S) proposing to deny its application, executed on August 30, 2000, for DEA Certificate of registration as a distributor of List I chemicals. The Order to Show Cause alleged in relevant part that granting the application of J & S would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h) and 824(a). The Order to Show Cause also notified J & S 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 J & S Distributors at its proposed registered location in Louisville, Kentucky. The return receipt indicated the Order to Show Cause was received on August 18, 2003, by Jeffrey D. Guernsey, president and owner of J & S. DEA has not received a request for hearing or any other reply from J & S or anyone purporting to represent the company in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since receipt of the Order to Show Cause, and (2) no request for hearing having been received, concludes that J & S has waived its hearing right. *See* Aqui Enterprises, 67 FR 12,576 (2002). After considering relevant material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53(c)

and (d) and 1316.67 (2004). 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. At the time that J & S Distributors submitted its application for DEA registration, phenylpropanolamine, also a List I chemical, was a legitimately manufactured and distributed product used to provide relief of the symptoms resulting from irritation of the sinus, nasal and upper respiratory tract tissues, and is also used in the illicit manufacture of methamphetamine and amphetamine. 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); Yemen Wholesale tobacco and Candy Supply, Inc., 67 FR 9997 (2002); Denver Wholesale, 67 FR 99,986 (2002).

The Deputy Administrator's review of the investigative file reveals that on August 30, 2000, J & S submitted an application for DEA registration as a distributor of the List I chemicals epheedrine, pseudoephedrine and phenylpropanolamine. The application was submitted on behalf of J & S by Jeffrey Guernsey. There is no information before the Deputy Administrator that J & S had sought to modify its pending application with respect to any of the listed chemical products it proposes to distribute. Upon receipt of the application, the DEA Louisville District Office initiated a pre-registration investigation of J & S in September of 2000.

According to the investigative file, during DEA's initial pre-registration inspection of J & S, the firm had no office or warehouse to conduct its business, and therefore, DEA was unable to immediately accomplish an inspection. However, DEA investigators conducted a second on-site pre-registration inspection of J & S on April 2, 2001, when the firm subsequently secured office and storage space in the vicinity of Louisville.

DEA's investigation revealed that J & S is a sole proprietorship operated by Jeffrey Guernsey, along with this father David Guernsey. The company is a wholesale distributor of key chains, pens, ceramics, lighters and commemorative items. Mr. Guernsey provided DEA with a product list of predominantly novelty items. A few ephedra based non-drug products were on the list. However, no health and beauty aids or non-regulated cough and cold products were included in their product list.

According to the DEA investigative file, Jeffrey Guernsey provided DEA investigators with a ''customer master list'' indicating he had 270 customers in about twenty states. Mr. Guernsey indicated he would acquire product directly from three manufacturers and further proposed to ship listed chemicals to those on his customer list by parcel service or truck shipment.

DEA investigators contacted several purported customers of J & S, who indicated they did do business with the company. However, none of these customers expressed any intention of purchasing listed chemical products from J & S.

DEA's subsequent review of the company's ''customer master file list'' revealed those entities were predominantly distributors or wholesalers located in other states. Of the customers listed, several did not have DEA registrations to handle List I chemical products, four had their DEA registrations revoked or suspended, another four were the subject of pending DEA registration actions, and another ten were known to DEA to be already receiving similar listed chemical products form multiple wholesale distributors. None of these wholesalers had any known retail customers other than convenience stores or gas stations.

In support of J & S' pending application for registration, on March 30, 2001, Jeffrey Guernsey sent DEA a ''Letter of Compliance'' along with a copy of the company's ''return policy on List I Chemicals.'' The letter was signed by Jeffrey Guernsey as President and David L Guernsey, who listed himself as ''Consultant.'' The letter outlined the experience of certain members of the Guernsey family in handling listed chemical products. However, Jeffrey Guernsey did not provide information as to any experience he personally had with List I products.

Pursuant to 21 U.S.C. 823(h), the Deputy Administrator may deny an application for Certificate of Registration if she determines that granting the registration would be inconsistent with the public interest as determined under that section. Section 823(h) requires 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 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 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 14,269 (1999); Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

The Deputy Administrator finds factors four and five relevant to J & S' pending registration application.

With respect to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant to Jeffrey Guernsey's apparent lack of experience in the handling of List I chemical products. The DEA investigative files shows that J & S is a retailer of general merchandise. While Jeffrey Guernsey provided information to DEA about members of his family who had experience in the handling of listed chemicals, it is unclear what role, if any, these family members would have in J & S' overall operation. Jeffrey Guernsey, J & S' sole proprietor and president, appears to be company's primary operator and he has not demonstrated that he possesses any previous experience handling listed chemical products. In prior DEA decisions, lack of experience in handling List I chemicals was a factor in determinations to deny applications for DEA registration. *See,* K&Z Enterprises, 69 FR 51,475 (2004); Matthew D. Graham, 67 FR 10,229 (2002); Xtreme Enterprises, Inc., 67 FR 76,195 (2002). Therefore, this factor similarly weights against granting J & S' application.

With respect to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor relevant to J & S' proposal to distribute listed chemical products to customers who have engaged in questionable business practices. As noted above, several of J & S' proposed customers have had DEA registrations revoked or suspended, or are already receiving listed chemical

products from multiple wholesale distributors. In addition, many of these purported customers have expressed no desire to purchase listed chemical products from J & S and the wholesalers distribute listed chemical products primarily to convenience stores and gas stations. While there are no specific prohibitions under the Controlled Substance Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found that business establishments such as gas stations and convenience stores constitute sources for the diversion of listed chemical products. *See, e.g.,* Sinbad Distributing, 67 FR 10,232 (2002); K.V.M. Enterprises, 67 FR 70,968 (2002) (denial of application based in part upon information developed by DEA that the applicant proposed to sell listed chemicals to gas stations, and the fact that these establishments in turn have sold listed chemical products to individuals engaged in the illicit manufacture of methamphetamine); Xtreme Enterprises, Inc., supra.

As noted above, there is no evidence in the investigative file that J & S has sought to modify its pending application with regard to the listed chemical products it seeks to distribute. Among the listed chemical products the firm intends to distribute is phenylpropanolamine. Accordingly, the Deputy Administrator also finds factor five relevant to J & S' request to distribute phenylpropanolamine and the apparent lack of safety associated with the use that product. DEA has previously determined that an applicant's request to distribute phenylpropanolamine constitutes a ground under factor five for denial of an application for registration. *See* William E. ''Bill'' Smith d/b/a B&B Wholesale, 69 FR 22,559 (2004); Shani Distributors, 68 FR 62,324 (2003). Based on the foregoing, the Deputy Administrator concludes that granting the pending application of J & S 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 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, previously submitted by J & S Distributors be, and it hereby is, denied. This order is effective November 22, 2004.

Dated: October 5, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–23706 Filed 10–21–04; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–40]

Sarfraz Mirza, M.D. Revocation of Registration

On March 2, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Sarfraz Mirza, M.D. (Respondent) of Melbourne, FL, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AM8413813, as a practitioner, pursuant to 21 U.S.C. 824(a)(3) and deny any pending applications for renewal of that registration pursuant to 21 U.S.C. 823(f). As a basis for revocation, the Order to Show Cause alleged that the Florida Department of Health had ordered an immediate suspension of Respondent's license to practice medicine in Florida and accordingly, he was not authorized to handle controlled substances in the state in which he is registered.

On May 17, 2004, through counsel, Respondent timely requested a hearing in this matter. On May 25, 2004, Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued the Government, as well as Respondent, an Order for Prehearing Statements.

In lieu of filing a prehearing statement, the Government filed Government's Request for Stay of Proceedings and Motion for Summary Disposition. The Government argued Respondent was without authorization to handle controlled substances in the State of Florida, and as a result, further proceedings in the matter were not required. Attached to the Government's motion was a copy of the State of Florida, Department of Health's Order of Emergency Suspension of License, indefinitely suspending Respondent's license to practice medicine in Florida, effective as of July 29, 2003.

On June 4, 2003, Judge Bittner issued a Memorandum to Counsel, staying the filing of prehearing statements and giving Respondent an opportunity to respond to the Government's motion. Respondent failed to file a response to the motion.

On August 10, 2004, Judge Bittner issued her 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 Disposition, finding the Respondent lacked authorization to handle controlled substances in Florida, the jurisdiction in which he is registered. Judge Bittner recommended that Respondent's DEA registration be revoked and any pending applications for renewal or modification of that registration be denied. No exceptions were filed by either party to Judge Bittner's Opinion and Recommended Decision and on September 15, 2004, the record of these proceedings was transmitted to the Office of the DEA Deputy Administrator.

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 Administrator adopts, in full, the Opinion and Recommended Decision of the Administrative Law Judge.

The Deputy Administrator finds that Respondent holds DEA Certificate of Registration, AM8413813. The Deputy Administrator further finds that, effective as of July 29, 2003, the State of Florida, Department of Health issued its Order of Emergency Suspension of License, suspending Respondent's authority to practice as a physician in the State of Florida. There is no evidence in the record indicating that this suspension has been lifted, stayed or that Respondent's license has been reinstated. As a result, he is not currently authorized to prescribe, dispense, administer, or otherwise handle controlled substances in the State of Florida, his place of DEA registration.

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 he conducts business. See 21 U.S.C. 802(21), 823(f) and 924(a)(3). This prerequisite has been consistently upheld. See Karen Joe Smiley, M.D., 68 FR 48,944 (2003); Dominick A. Ricci, M.D., 58 FR 51,104 (1993); Bobby Watts, M.D., 53 FR 11,919 (1988). Revocation is also appropriate when a state license has been suspended, but with a possibility of future reactivation. See Anne Lazar Thorn, M.D., 62 FR 12,847 (1997).

Here, it is clear Respondent currently lacks authority to handle controlled substances in Florida, the state in which he is registered with DEA as a practitioner. Therrefore, DEA does not have authority to maintain Respondent's DEA Certificate of Registration for his Florida practice or to grant any pending applications for renewal or modification of that registration.