Notice of Inspection. Because controlled substance records were not at this registered location Dr. Cronk was requested to come to the office and bring the records. Dr. Cronk responded and brought his remaining records to DEA investigators for their inspection.

6. Among the records provided was Dr. Cronk's controlled substance log, with the last entry in the log dated August 15, 2002. Dr. Cronk also produced an assortment of box tops, sample boxes, and other assorted pieces of paper and notes, including post-its, which he claimed were records of what had been dispensed to patients. Several of those boxes had multiple entries on them.

7. In the estimation of DEA investigators, Dr. Cronk's records were inaccurate, incomplete or irretrievable, thus making it impossible for them to conduct an audit of controlled substances. Dr. Cronk admitted his records were not in compliance with DEA requirements, that he was unaware of the requirement to conduct inventories of all controlled substances on hand every two years, and that he had not accomplished such inventories.

The Order to Show Cause was sent by certified mail to Dr. Cronk at his registered location in Quinlan, Texas and was accepted on his behalf on January 15, 2004. Despite subsequent written and verbal contacts by Dr. Cronk's office to the DEA Dallas Field Division, the agency's Office of Chief Counsel, as well as DEA Office of the Administrative Law Judges, there is no record of any request for a hearing having been received on behalf of Dr. Cronk.

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. Cronk 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. Cronk is currently registered with DEA as a practitioner. According to information received subsequent to the issuance of the aforementioned Order to Show Cause, on March 15, 2004, Dr. Cronk entered into an Agreed Order with the Texas State Board of Medical Examiners (Board). As recited in the Order to Show Cause, the Board similarly found that on May 21, 2003, Dr. Cronk ''* * * pled guilty to charges of possession of the controlled substance methamphetamine, a third degree felony. Conditions of [Dr. Cronk's plea] agreement included entrance to drug treatment * * *, probation for 5 years, fine of $1,300 and random drug screens.'' The Board cited additional concerns regarding Dr. Cronk's ''* * * unprofessional conduct, disciplinary action by [his] peers, and non-therapeutic prescribing.''

Accordingly, Dr. Cronk and the Board agreed, *inter alia,* that Dr. Cronk's state medical license be suspended until he demonstrated his fitness to safely practice medicine and completed various terms and conditions for reinstatement. Included among the Board imposed conditions was the requirement that Dr. Cronk complete psychological and neuro-psychiatric evaluations conducted by or under the direction of an approved psychiatrist to evaluate Dr. Cronk for substance abuse or an organic mental condition. More importantly, the Board specified that Dr. Cronk was to ''immediately cease from the practice of medicine in Texas.''

There is no evidence before the Deputy Administrator that Dr. Cronk has satisfied the conditions of the Board for reinstatement of his medical license, or that the Board suspension order has been stayed or lifted. In light of the suspension of his authorization to practice medicine in Texas, the Deputy Administrator also finds it reasonable to infer that Dr. Cronk is also without authorization to handled controlled substances in that state. As a result, Dr. Cronk is not entitled to maintain a DEA registration in Texas. *See, Miles J. Jones, M.D.,* 69 FR 40655 (2004); *Saihb S. Halil, M.D.,* 64 FR 33319, 3320 (1999).

Pursuant to 21 U.S.C. 824(a), the Deputy Administrator may revoke a DEA Certificate of Registration is she finds that the registrant has had his state license revoked or suspended and is no longer authorized to dispense controlled substances or has committed such acts as would render his registration contrary to the public interest as determined by factors listed in 21 U.S.C. 823(f). *Thomas B. Pelkowski, D.D.S.,* 57 FR 28538 (1992). Nevertheless, despite findings of the Board regarding Dr. Cronk's felony conviction with respect to his unlawful possession of controlled substances, and notwithstanding the other public interest factors for the revocation of his DEA registration asserted herein, the more relevant consideration here is the present status of Dr. Cronk's state authorization to handle controlled substances.

DEA does not have statutory authority under the Controlled Substance 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 824(a)(3). This prerequisite has been consistently upheld. *Daniel A. Maynard, D.O.,* 69 FR 22563 (2004); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993); *Bobby Watts, M.D.,* 53 FR 11919 (1998).

Here, it is clear that Dr. Cronk's Texas medical license has been suspended and by inference, he is currently not authorized under Texas law to handle controlled substances in his medical practice. Therefore, he is not entitled to a DEA registration in that state. As a result of a finding that Dr. Cronk lacks state authorization to handle controlled substances, the Deputy Administrator concludes that it is unnecessary to address further whether his DEA registration should be revoked based upon the public interest grounds asserted in the Order to Show Cause. *See Rory Patrick Doyle, M.D.,* 69 FR 11655 (2004); *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, BC2204131, issued to John A. Cronk, D.O., 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 November 22, 2004.

Dated: October 5, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–23713 Filed 10–21–04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03–05]

Express Wholesale Denial of Application

On September 27, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Express Wholesale (Respondent) proposing to deny its application for a 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 Respondent would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h) and 824(a).

Respondent, through counsel, requested a hearing on the issues raised by the Order to Show Cause and the matter was docketed before Administrative Law Judge Gail A. Randall. Following prehearing procedures, a hearing was held in Oklahoma City, Oklahoma on October 21–22, 2003. At the hearing both parties called witnesses to testify and introduced documentary evidence. Subsequently both parties filed Proposed Findings of Fact, Conclusions of Law, and Argument.

On May 18, 2004, Judge Randall issued her Recommended Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Opinion and Recommended Ruling), recommending that Respondent's application for a Certificate of Registration as a distributor of listed chemical products be denied. Neither party filed exceptions to the Opinion and Recommended Ruling and on June 24, 2004, Judge Randall transmitted the record of these proceedings to the 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 hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Ruling of the Administrative Law Judge. Her adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or any failure to mention a matter of fact or law.

By application dated August 23, 2001, Mr. Terry H. Kim, owner of Express Wholesale, located at 1913 Dyer Drive, Moore, Oklahoma, submitted an application for a DEA Certificate of Registration as a distributor of list I chemicals, seeking authority to distribute pseudoephedrine and phenylpropanolamine.

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 Respondent 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 for weight control. Phenylpropanolamine is also a precursor chemical 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); *Branex, Inc.,* 69 FR 8682 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.,* 67 FR 9997 (2002); *Denver Wholesale,* 67 FR 99,986 (2002).

On February 5, 2002, a DEA diversion investigator conducted a pre-registration inspection at Respondent's proposed registered location. It was situated in the residential duplex where Mr. Kim lives. He indicated he would store the listed chemical products in one-half of the unit's two-car garage, which did not have an internal secure storage container.

During the visit, the investigator provided Mr. Kim with a copy of DEA regulations and reference materials commonly referred to as the ''Red Sheet'' and the ''Green Sheet.'' These documents direct an applicant's attention to matters involving the diversion of ephedrine, pseudoephedrine and phenylpropanolamine to the illicit production of amphetamine and methamphetamine. The investigator additionally explained the meaning of both notices to Mr. Kim and asked if he had any questions about the notices.

When asked what products he intended to sell, Mr. Kim mentioned only Max Brand Pseudo 60 (''Max Brand'') and indicated that Max Brand would make up 30% of Respondent's overall business. He then asked the investigator if that was ''too much.'' After the on-site visit, Mr. Kim called the investigator several times inquiring as to the status of the application and stated he was losing business and customers because he could not provide them with the Max Brand product.

Mr. Kim also provided a customer list during the inspection and the investigator recognized many of the intended customers through her work on an unrelated criminal investigation during which she had visited 50 to 75 convenience stores in Oklahoma City, Oklahoma and Dallas, Texas. After being apprised the investigator was having problems confirming customers on his list, about a month later, Mr. Kim sent a supplemental list, which was shorter and had some different customers.

The investigator again recognized some of the store names as being involved with on-going criminal investigations. Several of the prospective customers were also on lists provided by other distributors with pending applications or were customers of current registrants. A significant portion of Respondent's prospective customers were convenience stores and gas stations.

During a brief follow-up visit on February 20, 2002, the investigator confirmed that Mr. Kim had now installed a wooden, padlocked storage container in the garage. The investigator concluded this would afford adequate physical security for storage of the list I chemical products.

Respondent's business consists primarily of supplying general merchandise to convenience stores and gas stations. When he began the registration application process, Mr. Kim was not aware that pseudoephedrine was used to manufacture methamphetamine. While Mr. Kim indicated he was aware of, and willing to abide by all requirements levied upon a DEA registrant, his testimony at the hearing reflected uncertainty as to his actual understanding of those requirements.

Mr. Kim did agree to exclude Max Brand from the product list if the application was granted. He also furnished 48 signed ''form letter'' type statements from owners or representatives of retail outlets in the Oklahoma City area, indicating they supported Respondent's DEA registration and would use its products only for legitimate purposes.

Methamphetamine use is a growing problem in the State of Oklahoma and pseudophedrine and ephedrine are combined with other products to manufacture methamphetamine. Convenience stores have been the primary source for the pseudoephedrine and ephedrine used in the illicit manufacturing of methamphetamine in the Oklahoma City area and some of these convenience stores are supplied through different wholesale distributors.

Max Brand Pseudo 60 is the precursor product predominantly encountered and seized at clandestine methamphetamine laboratories. Convenience 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. Large, nationally recognized chains such as Wal-Mart and Eckerd do not usually carry Max Brand products. While the record is unclear as to quantity and strength of products, in

Oklahoma City, Max Brand typically retailed for approximately $17.00 per bottle while other name brand cold and sinus products such as Tylenol, typically retailed for approximately $5.00 per bottle. Although local law enforcement officials in Oklahoma consider Max Brand the product of predominant concern, other brands have been discovered at area clandestine laboratories, including Action Brand, Bolt, Equate and Roxanne.

By declaration, the Government presented an expert witness in the area of statistical analysis of convenience stores and their sale of pseudoephedrine. Mr. Jonathan Robbin, a consultant in marketing information systems and databases, presented his evidence on behalf of the government as an expert in statistical analysis and quantitative marketing research. With respect to the expert analysis by Mr. Robbin, the Deputy Administrator adopts the following findings of fact, as set forth in Judge Randall's Opinion and Recommended Ruling.

Using the 1997 United States Economic Census of Retail Trade, Mr. Robbin tabulated data indicating that ''over 97% of all sales of non-prescription drug products,'' including non-prescription cough, cold and nasal congestion remedies, occur in drug stores and pharmacies, supermarkets, large discount merchandisers, mail-order houses and through electronic shopping. He characterized these five retail industries as ''the traditional marketplace where such goods are purchases by ordinary customers.''

Analyzing national sales data specific to over-the-counter, non-prescription drugs containing pseudoephedrine, Mr. Robbin characterized convenience stores as a ''nontraditional market'' for the sale of such products. His research and analysis show ''that a very small percentage of the sales of such goods occur in convenience stores—only about 2.6% of the HABC [Health and Beauty Care] category of merchandise or 0.05% of total in-store (non-gasoline) sales.'' He concluded that ''[c]onvenience stores, therefore, definitely constitute a 'non-traditional' market for the sale of over-the-counter, non-prescription drug pseudoephedrine products.''

He explained that this information supports DEA's conclusion that pseudoephedrine products distributed to this nontraditional market greatly exceeded the normal demand for such products at such retail outlets. He agreed that such excessive sales could be purchases of listed chemical products that were diverted to illicit uses.

With respect to Oklahoma wholesale pseudoephedrine sales of several distributors and over 300 of their retail customers, all of which were convenience stores, a July 2002 analysis by Mr. Robbin led to the conclusion ''that without evidence of the existence of immense numbers of legitimate customers, it was likely that the massive inventories of pseudoephedrine products purchased by these Oklahoma stores were being turned to illegal uses.''

In connection with Respondent's prospective customer list, Mr. Robbin also analyzed data accumulated from prior DEA cases regarding wholesale sales of pseudoephedrine products to convenience store retailers in Oklahoma. He found that more than two-thirds of Respondent's proposed customers had previously acquired ''excessive amounts of listed chemical products from one or more sources.'' He further opined that a large number of the stores from Respondent's list were not ''in the normal or traditional range of expectation in regard to the stocking and presumed sale of pseudoephedrine (Hcl) tablets.''

Four of the stores show an index of actual purchase rates of pseudoephedrine tablets in excess of 100% over the expected purchase rate. One store purchased a quantity valued at 208.9% over the expected legitimate purchase rate for such products. Given the small size of most convenience stores and the normal purchases of legitimate customers, Mr. Robbin concluded that ''[s]uch values are not possible in the normal commerce of these goods * * *''

He also concluded that the data pertaining to Respondent's proposed customer list indicates Respondent ''will predominantly serve retailers who already acquire excessive amounts of product from multiple sources'' and that Mr. Robbin's analysis clearly showed Respondent would not be selling listed chemical products to the traditional market for such over-the-counter drug products.

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 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.*, Direct Wholesale, 69 FR 11,654; Energy Outlet, 64 FR 14,269 (1999); Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

The Deputy Administrator finds factors one, four and five relevant to Respondent's pending registration application.

As to factor one, maintenance by the applicant of effective controls against diversion, the Deputy Administrator agrees with Judge Randall that the physical security of the proposed storage arrangement was adequate. However, DEA has previously held that registrants have a responsibility to maintain controls against diversion, beyond the confines of the mere physical security afforded the product. *See*, OTC Distribution Co., 68 FR 70,538 (2003).

Judge Randall found the record devoid of any indication that Mr. Kim had contemplated any measures by which he could ensure that potential customers would not acquire excessive listed chemical products that would ultimately be diverted. Lacking any business practices or systems that would act as a detection system, she concluded ''Respondent would be unable to effectively monitor suspicious purchase orders to alert him to the need to inquire as to the possibility of a proposed illicit distribution of the listed chemical product, or to alert him to the need to report such illicit distribution to the DEA.''

The evidence also failed to demonstrate that Mr. Kim grasped the need for monitoring the packaging of the listed chemical product he planned to distribute. The Deputy Administrator agrees with Judge Randall that ''DEA has legitimate concerns if a distributor elects to sell such bottles of listed chemical product, versus if a distributor elects to sell such product marketed in small quantity, blister packs.''

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]

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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)