

and directed him to immediately surrender his license to practice medicine. There is no evidence before the Deputy Administrator that the Consent Agreement has been modified, lifted or stayed or that Dr. Brockbank's Arizona medical license has been renewed or reinstated.

Pursuant to 21 U.S.C. 824(a)(3), the Deputy Administrator may revoke a DEA Certificate of Registration if she finds the registrant has had his state license revoked and is no longer authorized to dispense controlled substances in the jurisdiction of registration. Alternatively, revocation is authorized if the registrant 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). See *Thomas B. Pelkowski*, D.D.S., 57 FR 28,538 (1992).

Nevertheless, despite Dr. Brockbank's egregious prescribing activities, his grossly inappropriate conduct with female patients and the public interest factors that are implemented by such unprofessional and unlawful conduct, his lack of state authorization to handle controlled substances is dispositive of this matter.

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 824(a)(3). This prerequisite has been consistently upheld. See *Rory Patrick Doyle, M.D.*, 69 FR 11,655 (2004); *Dominick A. Ricci, M.D.*, 58 FR 51,104 (1993); *Bobby Watts, M.D.*, 53 FR 11,919 (1988).

Here, it is clear Dr. Brockbank surrendered his medical license and it is reasonable to infer that he is currently not authorized to handle controlled substances in Arizona and is therefore not entitled to a DEA registration in that state. As a result of the finding that Dr. Brockbank lacks any state authorization to handle controlled substances, the Deputy Administrator concludes 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 and Immediate Suspension of Registration. See *Gilbert C. Aragon, Jr.*, D.O., 69 FR 58,536 (2004); *Samuel Silas Jackson*, D.D.S., 67 FR 65,145 (2002); *Nathaniel-Aikens-Afful, M.D.*, 62 FR 16,871 (1997); *Sam F. Moore, D.V.M.*, 58 FR 14,428 (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, AB2053027, issued to Kevin Dean Brockbank, 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 June 26, 2006.

Dated: May 5, 2006.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03-26]

H & R Corporation; Denial of Application

On April 7, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to H & R Corporation (Respondent H & R) 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 substance that granting Respondent's application to distribute list I chemicals to what DEA has identified as the "gray market," 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 Mary Ellen Bittner. Following prehearing procedures, a hearing was held in Atlanta, Georgia on October 28, 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 December 3, 2004, 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), 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 January 11, 2005, judge Bittner 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.

In April 2002, Respondent, a Tennessee corporation owned by members of the Patel family, submitted an application for DEA Certificate of Registration as a distributor of list I chemicals, seeking authority to distribute pseudoephedrine, ephedrine and phenylpropanolamine. Mr. Ramu Patel (Mr. Patel) owns 50 per cent of the business and the remainder is owned by R. Patel's uncle, Hasmukh Patel (H. Patel) and his brothers, Mahendra and Kantibhai Patel. Mr. Patel and H. Patel are Respondent's only employees.

H & R also does business under the name "Tri-State Wholesale," a name used previously used by Elk International, Inc. (Elk International) when that company was operating out of the Chattanooga-area premises where H & R is now located. On May 1, 2001, Elk International filed an application for DEA registration as a distributor of list I chemicals. An Order to Show Cause was issued proposing to deny Elk International's application and H & R subsequently purchased the right to use the name "Tri-State Wholesale" from the company, along with its customer list. The Elk International matter was administratively closed as it was no longer in business at the location and H & R ultimately then submitted its application for registration, which is the subject of these proceedings.

H & R is a wholesale supplier of tobacco products, hair products and paper supplies to tobacco and convenience stores and what Mr. Patel referred to as "mom and pop" stores. Mr. Panel testified that he and his uncle previously owned retail tobacco stores/outlets in Dalton and Chickamauga, Georgia and his store had sold Mini-Thins and ephedrine products, along with tobacco products and other sundries.

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 which are legitimately manufactured and

distributed in single entity and combination forms as decongestants and bronchodilators, respectively. Both are used as precursor chemicals in the illicit manufacture of methamphetamine and amphetamine.

Phenylpropanolamine, also a list I chemical, is a legitimately manufactured and distributed product used to provide relief of the symptoms resulting from inflammation of the sinus, nasal and upper respiratory tract tissues and for weight control. Phenylpropanolamine is also used as a precursor in the illicit manufacture of methamphetamine and amphetamine. *See*, Gazaly Trading, 69 FR 22561 (2004). In November 2000, the United States Food and Drug Administration issued a public health advisory requesting drug companies to discontinue marketing products containing phenylpropanolamine, due to risk of hemorrhagic stroke. As a result, many pharmaceutical companies have stopped using phenylpropanolamine as an active ingredient.

As testified to by government witnesses and as addressed 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 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).

A Special Agent from DEA's Chattanooga, Tennessee, Resident Office testified regarding the rapid proliferation of clandestine methamphetamine laboratories in Tennessee and its adjoining states and described prevalent methods of local production. He also described the multiple health hazards and social costs stemming from the production and abuse of methamphetamine in Southeastern Tennessee. In sum, he deemed it "more than a legal issue; it is a terrible social issue."

As recognized in recent published final orders, Tennessee has led the DEA Atlanta Region in the number of clandestine laboratories seized. *See* Prachi Enterprises, Inc., 69 FR 69407 (2004); CWK Enterprises, Inc., 69 FR 69400 (2004). Further, the Chattanooga/Eastern Tennessee area, where H & R seeks to distribute chemicals, has a "substantial" methamphetamine abuse problem and it has been recognized that local "[d]istributors or retailers serving the illicit methamphetamine trade observe no borders and trade across state lines." *Id.*, 69 FR at 69401.

The Special Agent estimated that 80 to 90 percent of ephedrine and pseudoephedrine used by area methamphetamine manufacturers was obtained from convenience stores. More often than not, the ephedrine and pseudoephedrine products were "off name" brands, with Max Brand the most prevalent encountered at illicit laboratories. He also sees products at these sites with brand names such as Mini-Thins, Mini-Tabs, Pseudo-60's and Z-60's and the preferred pseudoephedrine is of 60 mg. strength.

The Special Agent testified that convenience stores are readily able to purchase ephedrine and pseudoephedrine and may use several distributors simultaneously for these products. Further, persons seeking to buy ephedrine and pseudoephedrine from convenience stores for illicit manufacturing typically go to many stores and buy small quantities from each, or recruit four or five people, who each purchase chemicals from a single store. Often store personnel allow the same individual to complete multiple purchases in a short period of time and some convenience stores even cater to manufacturers, selling other products used in the manufacturing process such as coffee filters, antifreeze, and Heet fuel which, for certain customers were even packaged in manufacturing "kits."

Diversion Investigators testified that, in general, persons purchasing pseudoephedrine and ephedrine for legitimate therapeutic purposes bought their products, packaged in blister packs and in smaller dosage units and strengths, at traditional drug stores, grocery stores and large discount stores.

By written declaration, a DEA Diversion Investigator contrasted the "traditional" market for list I chemicals with what DEA has termed the "gray market" for these products. The traditional market, characterized by a short distribution chain from manufacturer to distributor to retailer, typically includes large chain grocery stores, chain pharmacies, large convenience stores and large discount stores. The gray market is characterized by additional layers of distribution and includes such non-traditional retailers as small convenience stores, gas stations and other retail establishments where customers do not usually purchase over-the-counter medications. These non-traditional retailers typically sell higher-strength products in large package sizes, such as 100 or 120 count bottles of 60 mg. pseudoephedrine. The Diversion Investigator also identified the brand names found at clandestine laboratory seizures in disproportionate numbers.

They included Max Brand, Mini Two Way, MiniThin and Action-Pseudo.

A Group Supervisor from DEA's Nashville office testified that, in his view, the demand for pseudoephedrine and ephedrine for legitimate medical purposes did not justify the supply and much of these chemicals were being diverted at the convenience store level.

By declaration, the Government introduced evidence regarding ephedrine and pseudoephedrine sales and the convenience store market from Mr. Jonathan Robbin, a consultant in marketing information systems and databases, who is an expert in statistical analysis and quantitative marketing research.

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 purchased by ordinary customers.

Analyzing national sales data specific to over-the-counter, non-prescription drugs containing pseudoephedrine, Mr. Robbin's research and analysis showed 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 determined that the normal expected retail sales of pseudoephedrine tablets in a convenience store would range between \$10.00 and \$30.00 per month, with an average monthly sales figure of about \$20.00 and the sales of more than \$100.00 in a month would be expected to occur in a random sampling about once in one million to the tenth power, a number he characterized as nearly equivalent to the number of atoms in the universe. He further stated that the current convenience store gross margin in the health and beauty care category is about 40 percent, so that such a store could be expected to spend an average of \$12.00 per month acquiring its inventory of pseudoephedrine products from a distributor.

In October 2002, a pre-registration inspection was performed at H & R's facility by a DEA Diversion Investigator. Mr. Patel advised the Diversion Investigator that H & R had purchased its customer list from Elk International and its customers were mainly convenience stores and gasoline stations

located within 30 miles of Chattanooga. He identified several listed products H & R intended to sell which are normally sold in the traditional market. Of concern, he also advised the Diversion Investigator that the company would carry whatever products its customers wanted to buy. At the hearing, Mr. Patel then testified that customers had brought him samples of products they wanted and specifically asked for Max Brand Pseudo 60s. However, he had not yet identified a supplier for that product.

Max Brand Pseudo 60s has been identified by DEA as "the precursor product predominantly encountered and seized at clandestine methamphetamine laboratories" and convenience stores are the "primary source" for the purchase of "Max Brand products, which are the preferred brand for use by illicit methamphetamine producers * * *," Express Wholesale, 69 FR 62086, 62087 (2004); *see also* RAM, Inc. d/b/a/ American Wholesale Distribution Corp., 70 FR 11693 (2005).

The Diversion Investigator found Respondent's physical security adequate and its monitoring, storage and recordkeeping systems an improvement over Elk International's systems.

At the time of the hearing, Mr. Patel testified H & R then had about 385 customers. He also provided a list of 459 businesses, not all of whom were actual customers. At least 27 of these customers were located in cities some distance from Chattanooga, including Knoxville and Nashville, Tennessee; Atlanta, Summerville, Americus, Griffin, Rome, Tucker and Lakeland, Georgia; Huntsville, Chickasaw, Decatur and Mobile, Alabama; Myrtle Beach and Greenville, South Carolina; Gainesville, Florida; Kansas City, Missouri; and Woodstock, Illinois.

While Mr. Patel testified H & R would not sell listed chemicals to customers in Mobile, Woodstock and Gainesville, he did not specify whether he would sell to the customers at other distant locations on the list. He further testified H & R delivered to local customers but others, including those from Nashville and Atlanta, would have to come to the Chattanooga facility to pick up orders.

A DEA Special Agent testified he recognized at least ten names on Respondent's customer list as being under investigation by DEA, state or local law enforcement agencies for involvement in distribution of ephedrine or other chemicals associated with methamphetamine manufacturing. A Supervisory Investigator testified that Respondent's customer list also included distributors who were already registered to sell list I chemicals.

Mr. Patel testified he would not sell over-threshold quantities of list I chemicals to customers, but he could not say how much he would sell. He estimated that in addition to other products, he expected an average convenience store to order one or two dozen bottles of Mini Thins per month, which would probably retail at \$6.99 per bottle.

H. Patel did not testify, but submitted a post-hearing affidavit in which he stated that if Respondent's application were granted, they were willing to "work with DEA to limit the amount of ephedrine and single ingredient pseudoephedrine products we sell" and would not sell to customers being investigated by DEA. He also stated that H & R's customers requested that it carry listed chemicals, as they wanted to make their purchases from one distributor. H. Patel admitted having no experience selling listed chemicals at the wholesale level and did not know how much of these products H & R's customers might buy.

Mr. Patel testified that neither he nor his uncle had criminal records and the Government offered no evidence to the contrary.

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 11654 (2004); Energy

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

As to factor one, maintenance by the applicant of effective controls against diversion, the Deputy Administrator agrees with Judge Bittner that H & R's proposed physical security and recordkeeping arrangements were adequate. Judge Bittner also found that Respondent did not dispute the Government's evidence that convenience stores are a major source of diversion of list I chemicals.

Judge Bittner phrased the key issue in factor one as whether Respondent would sell listed chemicals to retailers who were likely to divert them. In concluding this factor weighed against registration, Judge Bittner took particular note that Mr. Patel's estimates of anticipated sales were several times larger than what Mr. Robbin's research indicated a convenience store would legitimately sell.

Additionally, at least ten customers on Respondent's list were under investigation for involvement in the distribution of chemicals associated with illicit methamphetamine manufacturing. Red flags were further raised by Mr. Patel's failure to specifically testify whether he would refuse to sell listed chemicals to customers located substantial distances from H & R's Chattanooga facility.

The Deputy Administrator is particularly concerned with Mr. Patel's willingness to sell "whatever" products his customers wanted. Coupled with the specific requests from its gray market customers that the company carry Max Brand Pseudo 60's, the preferred precursor of illicit manufacturers, the risk of diversion should the application be approved, is apparent. *See*, RAM, Inc. d/b/a American Wholesale Distribution Corp., *supra*, 70 FR 11693, 11694.

Judge Bittner acknowledged applicability of a previously published DEA final order in which registration was denied an applicant who, much like Respondent, was seeking registration to distribute list I chemicals in the gray market. In that case, Xtreme Enterprises, Inc., 67 FR 76195 (2002), there was no evidence the applicant's owner had failed to comply with Federal, State or local law or that she had any prior convictions relating to controlled substances or chemicals. Further, she was willing to provide adequate security for the listed chemicals.

However, the Deputy Administrator found the applicant's owner had only a rudimentary knowledge of what would constitute a suspicious order and no experience in the manufacture or distribution of listed chemicals. Most

significant, for purposes of this and similar cases, the Deputy Administrator also found that “[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.

Citing Xtreme Enterprises, Judge Bittner concluded that factor one (maintenance of controls against diversion), weighed against granting H & R’s application. The Deputy Administrator agrees, noting DEA has applied this analysis in numerous final orders published after Xtreme Enterprises was decided. *See, e.g.*, Express Wholesale, *supra*, 69 FR 62086; Value Wholesale, 69 FR 58548 (2004); K & Z Enterprises, Inc., 69 FR 51475 (2004); William E. “Bill” Smith d/b/a B & B Wholesale, 69 FR 22559 (2004); Branex Incorporated, *supra*, 69 FR 8682; Shop It for Profit, 69 1,311 (2003); Shani Distributors, 68 FR 62324 (2003).

Judge Bittner found Respondent had complied with applicable Federal, State and local laws and its owners have not been convicted of any crimes relating to controlled substances or listed chemicals. Thus, she concluded that factors two and three weigh in favor of registration. Based on the record that was before the Administrative Law Judge, the Deputy Administrator agrees. However, as discussed in depth under factor five, after the Opinion and Recommended Ruling was issued, state legislation was enacted making it illegal to sell tableted pseudoephedrine products in Tennessee, outside of licensed pharmacies. Thus, to the extent that Respondent’s Tennessee gray market customer base is no longer authorized to sell those products under state law, factor two is adversely impacted and weighs against registration.

With regard to factor four, the applicant’s past experience in distributing listed chemicals, Judge Bittner found that while Mr. Patel had previously sold listed chemical products in his retail tobacco outlet, neither of H & R’s owners/employees had experience selling listed chemicals at the wholesale level. Judge Bittner therefore found this factor weighed in favor of a finding that H & R’s registration would be inconsistent with the public interest. The Deputy Administrator agrees with that conclusion.

With regard to factor five, other factors relevant to public health and safety, Judge Bittner was “not persuaded

that Respondent will limit its sales of listed chemicals to the quantities that convenience stores are likely to sell to legitimate customers.” She thus found this factor also weighed against registration. The Deputy Administrator concurs.

Unlawful methamphetamine production and use is a growing public health and safety concern throughout the United States and specifically in the localities where Respondent intends to do business. Pseudoephedrine and ephedrine are the precursor products used to manufacture methamphetamine and area laboratory operators predominantly acquire their precursor chemicals from the customer base Respondent seeks to serve. While the Patels indicated some intent to avoid contributing to this scourge, the risk of diversion once listed chemicals enter the gray market is real, substantial and compelling.

The Deputy Administrator concludes Judge Bittner correctly applied DEA precedent. As in Xtreme Enterprise, *supra*, the Respondent’s owners’ lack of criminal records, their previous compliance with the law and any professed willingness to comply with regulations and guard against diversion, are far outweighed by the intent to sell ephedrine and pseudoephedrine, almost exclusively, in the gray market.

This reasoning has been consistently applied by the Deputy Administrator in a series of recently published final orders denying registration to potential gray market distributors. *See*, RAM, Inc. d/b/a American Wholesale Distribution Corp., *supra*, 70 FR 11693; Al-Alousi, Inc., 70 FR 3561 (2005); Volusia Wholesale, *supra*, 69 FR 69409; Prachi Enterprises, Inc., *supra*, 69 FR 69407; CWK Enterprises, Inc., 69 FR 69400 (2004); J & S Distributors, 69 FR 62089 (2004); Express Wholesale, *supra*, 69 FR 62086; Absolute Distributing, Inc., 69 FR 62078 (2004); Value Wholesale, *supra*, 69 FR 58548 (2004); John E. McRae d/b/a J & H Wholesale, 69 FR 51480 (2004).

While not addressed in the Opinion and Recommended Ruling, the Deputy Administrator notes that state legislatures throughout the United States are actively considering legislation designed to impede the ready availability of precursor chemicals. Many of these proposals are similar to legislation enacted by the State of Oklahoma, titled the “Oklahoma Methamphetamine Reduction Act of 2004.” Under that measure, as of April 6, 2004, pseudoephedrine tablets were designated as Schedule V controlled substances and may be sold only from licensed pharmacies within that state.

As a result, it is prohibited in Oklahoma to sell these products from gray market establishments, such as independent convenience stores, which have contributed so much to the scourge of methamphetamine abuse. *See, e.g.*, Express Wholesale, *supra*, 69 FR at 62809 [denying DEA registration to an Oklahoma gray market distributor, in part, because of new state restrictions].

A review of data for 2004 reveals the Oklahoma law has resulted in an apparent reduction in the number of seizures involving clandestine methamphetamine laboratories in that state. These developments are encouraging and represent an important step in the ongoing battle to curb methamphetamine abuse in the United States. State legislation, such as Oklahoma’s, reflects a positive trend and growing recognition that the diversion of precursor chemicals through the gray market insidiously impacts public health and safety. *See, e.g.*, Tysa Management, d/b/a Osmani Lucky Wholesale, 70 FR 12732, 12734 (2005) [denying registration to intended Oklahoma distributor, in part, on basis of enactment of recent state legislation]; Express Wholesale, *supra*, 69 FR at 62089.

Of particular consequence to H & R and similarly situated Tennessee applicants and registrants, after Judge Bittner signed her Opinion and Recommended Ruling, legislation was enacted by the State of Tennessee that is patterned after the Oklahoma initiative. That legislation (Senate Bill 2318/House Bill 2334), collectively known as the “Meth-Free Tennessee Act of 2005,” was signed into law by Governor Phil Bredeson on March 31, 2005, and makes it unlawful for establishments, other than licensed pharmacies, to sell tableted pseudoephedrine products in Tennessee after April 1, 2005. This includes both name brand and off-name brand products.

Accordingly, Respondent’s entire intended Tennessee customer base is now prohibited by state law from selling the pseudoephedrine products H & R seeks DEA registration to distribute. This adversely implicates factors five and two and weighs heavily against registration. *See*, Tysa Management, d/b/a Osmani Lucky Wholesale, *supra*, 70 FR at 12734; Express Wholesale, *supra*, 69 FR at 62089.

Factor five is also relevant to H & R’s proposal to distribute chemicals to customers under criminal investigation. The conduct of a potential customer has previously been deemed a relevant consideration under factor five. *See*,

Gazaly Trading, *supra*, 69 FR 22561; Shani Distributors, *supra*, 68 FR 62326.

Finally, it is noted that Respondent seeks to distribute phenylpropanolamine. Accordingly, the Deputy Administrator finds factor five relevant to H & R's request to distribute phenylpropanolamine and the 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, J & S Distributors, *supra*, 69 FR 62089; Gazaly Trading, *supra*, 69 FR 22561; William E. "Bill" Smith d/b/a B & B Wholesale, *supra*, 69 FR 22559; Shani Distributors, *supra*, 68 FR 62324.

Based on the foregoing, the Deputy Administrator concludes that granting Respondent's 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 CFR 0.100(b) and 0.104, hereby orders that the pending application for a DEA Certificate of Registration, previously submitted by H & R Corporation, be, and it hereby is, denied. This order is effective June 26, 2006.

Dated: May 5, 2006.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sidney S. Loxley, M.D.; Revocation of Registration

On January 25, 2005, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Sidney S. Loxley, M.D. (Dr. Loxley) of Chesapeake, Virginia. Dr. Loxley was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AL6366428, as a practitioner, and deny any pending applications for renewal or modification of that registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) on the basis that his continued registration would be inconsistent with the public interest. Dr. Loxley was further notified that pursuant to 21 U.S.C. 824(d), his DEA registration was

being immediately suspended as an imminent danger to the public health and safety.

The Order to Show Cause and Immediate Suspension of Registration alleged that Dr. Loxley had been the subject of two prior disciplinary proceedings before the Virginia Board of Medicine (Virginia Board). In June 1993, his medical license had been suspended for 16 months as a result of his abusing the patient-doctor relationship by engaging in a sexual relationship with a minor and for a related misdemeanor conviction of contributing to the delinquency of a minor. His state license was reinstated in October 1994 but in a subsequent disciplinary proceeding occurring in October 2003, it was placed on probation for a period of not less than three years. At that time the Virginia Board found, along with several controlled substance recordkeeping violations reflecting gross incompetence, that Dr. Loxley had improperly prescribed controlled substances to his wife, who was not his patient and was chemically dependent. As a condition of his probation, Dr. Loxley was directed to complete a Board approved course in the proper prescribing of controlled substances.

The Order to Show Cause and Immediate Suspension of Registration alleged, in sum, that Dr. Loxley had been issuing prescriptions for large amounts of controlled substances to individuals without the physical examinations, testing or evaluations which are consistent with a legitimate doctor-patient relationship. These prescriptions were not issued for legitimate medical purposes or in the usual course of professional treatment, thus violating 21 CFR 1306.04 and 21 U.S.C. 841(a). It was further alleged that between September 2003 and May 2004, on ten separate occasions Dr. Loxley issued prescriptions under these circumstances to a DEA Special Agent and a confidential source who had been posing undercover as patients. Profiles obtained from area pharmacies covering the period between August and December 2004 indicated he was continuously prescribing large quantities of controlled narcotic substances, primarily oxycodone and hydrocodone, in 120 tablet quantities to patients without apparent legitimate medical reasons and supplier records shows that Dr. Loxley was the largest orderer of Demerol (meperidine), among all orthopedic surgeons in the Virginia Tidewater area.

Finally, it was alleged that four patients of Dr. Loxley had died while under his care as a result of possible excessive prescribing, that he prescribed

controlled substances while under the influence of alcohol and had recently been convicted of driving while intoxicated in state court.

According to the investigative file, the Order to Show Cause and Immediate Suspension of Registration was personally served on Dr. Loxley by a DEA Diversion Investigator on January 27, 2005. More than thirty days have passed since service of the Order to Show Cause and Immediate Suspension of Registration and DEA has not received a request for hearing or any other reply from Dr. Loxley 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. Loxley, and (2) not request for hearing having been received, concludes that Dr. Loxley 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 the Dr. Loxley is currently registered with DEA as a practitioner under DEA Certificate of Registration AL 6366424. According to information in the investigative file, on January 20, 2005, and indictment was unsealed by order of the United States District court, Eastern District of Virginia (Norfolk), charging Dr. Loxley with 91 felony counts relating to the unlawful distribution and dispensing of controlled substances without a legitimate medical purpose under 21 U.S.C. 841(a)(1) and (b)(1)(C). The indictment includes four counts alleging that a death had resulted from Dr. Loxley's unlawful distribution and dispensing. On the date the indictment was unsealed, Dr. Loxley was arrested and he remains in custody pending trial in the matter of *USA v. Sidney Loxley* (Case No. 2:04-cr-00236-WDK-JEB-ALL).

On February 25, 2005, the Virginia Board notified Dr. Loxley that an informal conference had been scheduled to address allegations of multiple violations of state laws and regulations governing the practice of medicine and surgery and an allegation that he was unfit for the performance of his professional obligations and duties and unable to practice medicine with reasonable skill and safety. In response, Dr. Loxley advised the Virginia Board that he was currently unable to address