

The investigative file also reveals that in response to the Michigan Board's June 2001 Order of Summary Suspension, and effective August 8, 2001, Dr. Deshmukh and the Ohio Medical Board entered into a Consent Agreement. Among the terms agreed to by the parties was the indefinite suspension of Dr. Deshmukh's medical license in that state.

There is no evidence in the record that Dr. Deshmukh's licenses to practice medicine in Michigan and Ohio have been reinstated. Therefore, the Deputy Administrator finds that since Dr. Deshmukh is not currently authorized to practice medicine in either jurisdiction, it is reasonable to infer that she is not authorized to handle controlled substances in those states.

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 *Joseph Thomas Allevi M.D.*, 67 FR 35581 (2002); *Carla Johnson, M.D.*, 66 FR 52939 (2001); *Graham Travers Schuler, M.D.*, 65 FR 50570 (2000); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993); *Bobby Watts, M.D.*, 53 FR 11919 (1988).

Here, it is clear that Dr. Deshmukh is not licensed to handle controlled substances in Michigan and Ohio, the states in which she seeks registration and is currently registered with DEA, respectively. Therefore, she is not entitled to a DEA registration in those states.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, BD4361692, issued to Minakshi B. Deshmukh, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that Dr. Deshmukh's pending application for DEA registration dated June 5, 2001, is denied. This order is effective January 23.

Dated: November 20, 2002.

John B. Brown, III

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

K-Nine Detectives; Denial of Application

On July 16, 2001, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to K-Nine Detectives (Respondent), proposing to deny its application, executed on February 14, 2000, for DEA Certificate of Registration as a researcher. The application was submitted on behalf of the Respondent by its owner, Shane Kessler (Mr. Kessler). The Order to Show Cause alleged that granting the Respondent's application would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).

The Order to Show Cause was delivered by certified mail on July 23, 2001, and the Respondent timely requested a hearing. However, after the matter was docketed before Administrative Law Judge Mary Ellen Bittner, and the Government submitted its prehearing statement, the Respondent withdrew its request for hearing. Accordingly, Judge Bittner terminated all proceedings before her and the matter was subsequently transmitted to the Deputy Administrator for Final Agency Decision.

In light of the withdrawal of its request for hearing, the Deputy Administrator finds that the Respondent has waived its hearing right. After considering material from the investigative file in this matter, the Deputy Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Mr. Kessler submitted a DEA registration application seeking to register K-Nine Detectives at his home address in Tigard, Oregon. The Respondent sought authorization to handle controlled substances in Schedules I through V as a researcher. Included among the Schedule I controlled substances the Respondent sought to handle were heroin and marijuana. The Respondent also requested authorization to handle Schedule II controlled substances, cocaine, opium, powdered opium and methamphetamine.

Upon submission of Respondent's application, Mr. Kessler informed the DEA field office in Portland, Oregon that he planned to hire himself and his dogs to perform drug searches at schools, factories, and other private

premises. DEA learned that Mr. Kessler had no previous experience with training dogs for purposes of drug detection.

In light of his lack of experience in drug-detection, a DEA diversion investigator urged Mr. Kessler to contact local law enforcement authorities to discuss his planned business activities. The investigator also requested that Mr. Kessler determine whether there was a need for such services in his community as well as in other parts of Oregon. DEA subsequently learned from the Tigard Chief of Police and the Sheriff of Washington County (of which the city of Tigard is a part) that both sought to dissuade Mr. Kessler from his planned business venture because there was adequate coverage by law enforcement canine drug teams in the area.

Mr. Kessler also submitted with his registration application the first of three research protocols. In the original protocol, Mr. Kessler reported that he would have on hand up to five lbs. each of heroin, marijuana, cocaine, opium, methamphetamine, and crack cocaine. In a subsequent revised protocol sent to DEA, Mr. Kessler then reduced the drug quantities to ½ lb. of marijuana and ¼ lb. of the remaining substances. In the third protocol, Mr. Kessler again revised the quantities of controlled substances that he would have on hand. On all three protocols, Mr. Kessler stated that his canines would search for drugs and explosives, even though he previously reported that his dogs were trained to detect only drugs and not explosives. In addition, while the Respondent's DEA registration application sought authorization to handle controlled substances in Schedule I through V, the research protocols provided by the Respondent only made mention of drugs in Schedules I and II.

DEA obtained additional information from the Washington County Sheriff's Department and the Drugs and Vice Division of the Portland Police Bureau (which both handle drug-detecting dogs) regarding the need for certifications for drug detecting dogs. DEA was informed that for purposes of court testimony, the handler of a drug-detecting dog would have to show that the dog had passed, at minimum, an annual certification. However, the Oregon Police Canine Association, the primary certifying organization for drug-detecting dogs, does not provide certifications for non-law enforcement dog handlers. The Deputy Administrator finds that the Respondent is not affiliated with any law enforcement entities.

During a regulatory inspection of its proposed registered location on April 24, 2001, DEA learned that the

Respondent does not have any customers for which it will perform searches with dogs. Mr. Kessler also stated that he had not spoken to any business owners about hiring his company to perform drug-detection services. However, he informed DEA investigations that he had spoken to the principal and vice-principal of Century High School in Hillsboro, Oregon about hiring his company to perform drug searches of lockers and the school's personnel seemed receptive to the proposal. Mr. Kessler further informed DEA investigators that he had also approached the vice-principals of Tigard and Beaverton High School about performing drug detection services at their institutions.

Despite Mr. Kessler's representations, DEA investigators subsequently learned from the principal of Century High that the governing board for the entire Hillsboro school district decided against general searches through any of the district's schools through the use of a drug-detecting dog. The principal stated that if circumstances warranted a search, they would utilize the services of drug dogs trained by the Washington County Sheriff's Department. The principal added that this arrangement would not cost the school any additional funds. DEA investigators also learned that Mr. Kessler had never approached the vice-principal of Century High School regarding the use of drug searching dogs.

The Deputy Administrator finds that a DEA investigator also contacted officials from Tigard and Beaverton High Schools. Both schools reported that they had not been approached by Mr. Kessler regarding the use of drug detection dogs. In addition, both institutions had contingency plans in place for drug detection that relied upon the services of city and county law enforcement authorities.

The Deputy Administrator also finds that a DEA investigator consulted with several law enforcement officers with experience in conducting drug searches with canines. One of the persons interviewed was a detective for the Gresham (Oregon) Police Department who was also a Task Force Officer (TFO) for DEA's Airport Task Force and a former President and "Master Trainer" of the Oregon Police Canine Association. Upon his review of the quantities of controlled substances the Respondent proposed for use in training, the officer found that there was no rationale for possessing more than 50 grams total of any drug for on-going dog training purposes. The officer concluded that the quantities outlined in the Respondent's Research Protocols

far exceeded those required to conduct drug-detection training with canines.

The Deputy Administrator also finds that DEA investigators interviewed individuals from the private sector involved in dog training for drug-detection purposes. The general response from those entities was that there is no demand in the private sector for drug-detection services involving schools and businesses.

The Deputy Administrator also finds that DEA investigators also consulted with the Chief Deputy of the Washington County Sheriff's Office regarding the Respondent's proposed registration with DEA. The Chief Deputy expressed concerns about Respondent's plan to possess controlled substances and conduct training at specified locations such as schools and businesses. Among his concerns was that the Respondent's registered location would be within a few hundred yards of a middle school. The Chief Deputy expressed further concern that introduction of controlled substances in close proximity to a school would pose a health and safety threat to schoolchildren. Finally, the Washington County Sheriff's Office further informed DEA of information received that the District Attorney of Washington County would not prosecute any case where controlled substances had been seized as a result of a search conducted by the Respondent.

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

- (1) The recommendation of the appropriate state licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable state, federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health or safety.

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 he deems appropriate in determining whether a registration should be revoked or an application for

registration denied. See Henry J. Schwartz, Jr., M.D., 54 FR 16422 (1989).

It is clear that granting the Respondent's application for DEA Certificate of Registration would be inconsistent with the public interest. The Respondent has requested authorization to handle controlled substances in Schedules I through V although its research protocols only reference drugs in Schedules I and II. The Deputy Administrator finds that the drugs outlined in the protocols are in quantities far in excess of what is required to conduct research involving canines.

The Deputy Administrator finds that the Respondent seeks to engage in an activity that is not needed in the area in which it seeks registration. The Deputy Administrator also finds that the Washington County Sheriff's Department, the Drugs and Vice Division of the Portland Police Bureau, and other local law enforcement entities have narcotics detection canines of sufficient numbers to service the needs of the law enforcement community, businesses and private citizens. DEA has previously found such factor relevant in denying an application for registration as a researcher. See, *e.g.*, Albanoski, Broughton & Associates International, 57 FR 4646 (1992); K-9 Drug Detection Services of Florida, Inc., 56 FR 5238 (1991).

DEA has also found that grounds exist to deny an application for registration as a researcher where, as in this matter, the applicant lacks relevant experience in training canines for drug detection purposes. Angelos Michalatos d/b/a/ Contraband Searches and Investigation, 54 FR 48161 (1989).

No evidence has been submitted on behalf of the applicant. Therefore, the Deputy Administrator concludes that the Respondent has failed to demonstrate a need for, or the ability to perform, the activity for which it sought registration to handle controlled substances. Based on the above, the Deputy Administrator concludes that the Respondent's registration would be inconsistent with the public interest and therefore, its application for registration must be denied.

Accordingly, the deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 28 CFR 0.100(b), hereby orders that the application for DEA Certificate of Registration as a researcher submitted by Shane Kessler on behalf of K-Nine Detectives be, and it hereby is, denied. This order is effective January 10, 2003.

Dated: November 20, 2002.

John B. Brown, III,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Xtreme Enterprises, Inc.: Denial of Request for Registration To Handle List I Chemicals

I. Background

On December 15, 2000, Xtreme Enterprises, Inc., (Respondent) applied to be registered with the Drug Enforcement Administration (DEA) as a distributor of the list I chemical ephedrine. After an investigation by DEA investigators, on April 6, 2001, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause why DEA should not deny Respondent's application. On May 2, 2001, in response to the OSC, Rhonda J. Bryngelson, the owner of Respondent, requested and administrative hearing.

The requested hearing was held in Milwaukee, Wisconsin on November 7, 2001, before Administrative Law Judge Mary Ellen Bittner. At the hearing, each party called witnesses to testify and introduced documentary evidence. After the hearing, each party submitted Proposed Findings of Fact, Conclusions of Law and Argument. On April 3, 2002, the Administrative Law Judge issued her Recommended Rulings, Findings of Fact, Conclusions of Law and Decision, recommending that the Deputy Administrator grant Respondent's application for registration. Neither party filed exceptions to the Administrative Law Judge's Findings.

On May 7, 2002, the Administrative Law Judge certified and transmitted the record to the Deputy Administrator of DEA. The record included the Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, the findings of fact and conclusions of law proposed by all parties, all of the exhibits and affidavits, and the transcript of the hearing sessions.

II. Final Order

The Deputy Administrator does not adopt the Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge. The Deputy Administrator has carefully reviewed the entire record in this matter, as defined above, and hereby issues this final rule and final order prescribed by 21 CFR 1316.67 and 21 CFR 1304.46,

based upon the following findings of fact and conclusions.

At the hearing, John N. Uncapher, then chief of the Domestic Chemical Control Unit at DEA, credibly testified that the primary objective of his unit is to reduce or curtail the diversion of listed chemicals and other clandestine lab supplies, register applicants if their registration is consistent with the public interest and stop imports of listed chemicals where there is reason to believe that the imports may be diverted to the unlawful manufacture of controlled substances. After the enactment of the Chemical Diversion and Trafficking Act in 1988 (CDTA), the law imposed reporting, record keeping and import/export notification requirements for regulated transactions in controlled chemicals. The law only applied to bulk ephedrine, however. The law excepted single-entity over the counter (OTC) ephedrine products.

Mr. Uncapher also testified that ephedrine has a therapeutic use in both OTC and legend drug products. Ephedrine is lawfully marketed under the Federal Food, Drug and Cosmetic act for OTC use as a bronchodilator used in the treatment of asthma. Ephedrine is also available OTC in combination with other active ingredients. As a legend drug (*i.e.* dispensed pursuant to a physician's order or prescription,) ephedrine is used in injectable form in hospitals as part of an anesthesiology kit. Ephedrine has the beneficial effect of increasing low pressure very rapidly in the event of hypotensive crisis.

By the late 1980's traffickers and clandestine lab operators discovered the ease with which ephedrine could be purchased in large quantities and converted to methamphetamine. In 1994, however, the Domestic Chemical Diversion Control Act of 1993 (DCDCA) removed the record keeping and reporting exemption for single entity ephedrine and required registration of distributors, importers and exporters of all ephedrine products and other list I chemicals.

The passage of the DCDCA led to the increased diversion of pseudoephedrine tablets for the illicit production of methamphetamine. This led to the enactment of the Comprehensive Methamphetamine Control Act of 1006 (MCA), which expanded regulatory control of lawfully marketed drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine.

Mr. Uncapher also testified that he had reviewed the file concerning Respondent's application. The file revealed that Respondent's owner informed DEA that the Respondent

would distribute ephedrine products to entities that are considered part of the "non-traditional market" (*i.e.*, gas stations and convenience stores). Mr. Uncapher also testified that one of Respondent's proposed suppliers of ephedrine is Proactive Labs, Inc., a DEA registered distributor of list I chemicals located in Austell, Georgia. On November 9, 1999 and again on January 24, 2001, Proactive Labs was the recipient of warning letters from DEA informing the company that list I chemicals supplied by the firm had been associated with the illicit production of methamphetamine in various parts of the United States. Mr. Uncapher concluded that Respondent's ephedrine products will likely be diverted to illicit use, and the Respondent would therefore become a major source of listed chemicals for illicit traffickers of methamphetamine.

Guy J. Hargreaves testified by written declaration that he is a Special Agent at DEA and has had considerable experience in the investigation of clandestine methamphetamine laboratories. He routinely conducts nationwide methamphetamine and clandestine laboratory safety presentations to civil groups, anti-drug coalitions, and law enforcement groups on safety awareness, chemical hazards, and the latest intelligence in clandestine laboratory investigations. Mr. Hargreaves testified that until the early 1990's, the methamphetamine trade was fragmented into small organizations dominated by outlaw motorcycle gangs. Afterwards, organized methamphetamine traffickers from Mexico began to monopolize the production and delivery of methamphetamine to make an inexpensive and highly abusable product. An expanded population of methamphetamine abusers quickly realized the potential for easily producing methamphetamine for personal or local use by using the ephedrine/pseudoephedrine reduction technique. As a result, the proliferation of smaller laboratories has reached epidemic proportions, on both the west coast and in several Midwestern states. S/A Hargreaves further testified that most drugs in illicit traffic are products of illicit processing or synthesis. In the methamphetamine trade, chemicals are often accumulated and processed by cooks in small scale production labs or by organized crime groups which operate much larger scale clandestine laboratories.

Mr. Hargreaves also testified that clandestine laboratory operators employ a variety of methods to conceal from law enforcement their purchases of