

profit. Other: None. *Abstract:* Title 21, CFR, Section 1312.11 requires any registrant who desires to import certain controlled substances into the United States to have an import permit. In order to obtain the permit, an application must be made to the Drug Enforcement Administration on DEA Form 357.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: There are approximately 49 respondents who will complete the form within approximately 15 minutes per response. A respondent may submit multiple responses.

(6) An estimate of the total public burden (in hours) associated with the collection: There are 88 estimated burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Department Deputy Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: June 29, 2004.

Brenda E. Dyer,

*Department Deputy Clearance Officer,
Department of Justice.*

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Robert Brehm d/b/a Infinite Pills; Denial of Application

On October 15, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Robert Brehm (Mr. Brehm), proposing to deny his application for DEA Certificate of Registration as a distributor. The Order to Show Cause alleged that granting Mr. Brehm's application would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(b) and (e). The show cause order also notified Mr. Brehm that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Mr. Brehm at his address of record and DEA received a signed receipt indicating that it was received on October 20, 2003. DEA has not received a request for hearing or any other reply from Mr. Brehm or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Mr. Brehm is deemed to have waived his hearing right. 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 Mr. Brehm submitted a DEA registration application dated May 30, 2000, under the business name "Infinite Pills" at a location in Sellersville, Pennsylvania. Mr. Brehm sought a DEA registration to handle controlled substances in Schedules I through V as a distributor.

On June 21, 2000, a diversion investigator from DEA's Philadelphia Field Division (the Philadelphia Division) conducted an on-site pre-registration inspection of the applicant's proposed business location. The inspection revealed the proposed registered location to be a private, residential townhouse owned by the mother of Mr. Brehm. DEA's investigation further revealed that at the time he submitted an application for DEA registration, Mr. Brehm was a 20-year old male who had never operated a business and had no working experience or knowledge about the pharmaceutical (controlled substance) industry.

DEA's inspection further revealed that at the time of DEA's pre-registration inspection, Mr. Brehm had yet to determine what controlled substance products he would be handling, or from whom he would purchase them. Mr. Brehm was unable to distinguish products that are controlled substances (*i.e.*, narcotics, barbiturates, *etc.*) as opposed to non-controlled drugs. In addition, Mr. Brehm had no potential customers and had not surveyed local pharmacies or practitioners in his area to determine whether or not he could establish a customer base. Finally, DEA's inspection revealed that Mr. Brehm had not developed a recordkeeping/invoicing system for his proposed business.

As a result of its inspection, on July 20, 2000, the Philadelphia Division sent a letter to Mr. Brehm notifying him that DEA would seek the denial of his application, and further requested that Mr. Brehm voluntarily withdraw his application. Mr. Brehm informed the Philadelphia Field Division through a subsequent telephone message of his intention not to withdraw his application.

In late August 2000, the Philadelphia Division received information from the agency's Pittsburgh (Pennsylvania) office that a DEA registration number belonging to a physician from western Pennsylvania had been transferred to an address in Sellersville, Pennsylvania in mid-July 2000. According to the investigative file, someone using this registration number and claiming to be the doctor was attempting to obtain controlled substances from a drug manufacturer located in Aurora, Colorado. DEA's investigation revealed that the physician had not requested a transfer of his DEA registration and was unaware of any such transfer. It was later determined that the Sellersville address from which an attempt was made to obtain controlled substances was the same address that appeared on Mr. Brehm's May 30, 2000, application for DEA registration.

On August 28, 2000, a DEA diversion investigator spoke with a representative of the Colorado drug manufacturer. The company representative stated that on July 28, 2000, she received a call from a man identifying himself as a physician by the name of "Louis Nichamin." Several days later, the company received an order from "Dr. Nichamin" on a Kinko's letterhead fax. When the drug company representative subsequently called the telephone number provided to her by "Dr. Nichamin," she was told by the person answering the call that "* * * he (Dr. Nichamin) doesn't live here anymore." On August 18, 2000, the company representative received another call from a man purportedly on Dr. Nichamin's behalf, who asked the status of an earlier order. The man was described as speaking with an "Indian accent." When the company representative asked the name of the person placing the call, the caller identified himself as "Bob Brehm."

On September 1, 2000, the drug company representative called the Philadelphia Division informing that office that she had just received another call from a person representing himself as "Dr. Nichamin." This time the caller spoke with no discernable accent. When the caller asked about the order placed by "Dr. Nichamin", the drug company representative again asked the caller to identify himself. The caller identified himself as Robert Brehm. When the drug company representative stated her unfamiliarity with the caller, the caller stated he was "Bob Brehm", the same person that she (the drug company representative) had spoken to on an earlier occasion.

The drug company representative then asked the caller for a number

where he could be reached. Mr. Brehm again provided that same number that was purportedly provided on behalf of Dr. Nichamin on a prior occasion. When the drug company representative told Mr. Brehm of her earlier unsuccessful attempt at reaching Dr. Nichamin at the number provided, Mr. Brehm stated that he and the doctor had been "roommates", but the doctor had moved into a house. It is unclear from the investigative file whether any controlled substances were distributed to Mr. Brehm pursuant to the orders that were placed.

On September 5, 2000, the drug company representative informed DEA that a second order for controlled substances was received on behalf of Dr. Nichamin, and originating from Mr. Brehm's address of record in Sellersville. The controlled substances were ordered, in varying quantities, via unsigned DEA Order Forms. Among the controlled substances ordered were Morphine Sulfate, Hydromorphone, OxyCodone, Hydrocodone Bitartrate, Meperidine, Testosterone Micro, Testosterone Cypionate, Testosterone Propionate and Ketamine.

DEA's investigation further revealed that on September 1, 2000, the Pennridge Regional Police received a complaint from Robert Brehm that his father had stolen his (Mr. Brehm's) gun. It was later determined by law enforcement authorities that Mr. Brehm attempted to shoot his father with the gun. According to the police investigative report, Robert Brehm had an altercation with his father inside the family's residential address (the same address used for application purposes with DEA), where Mr. Brehm fired six rounds from his .380 pistol at his father. At the time the police arrived at the townhouse, it was noted that Robert Brehm was " * * * sweating profusely, had a blank stare, and was displaying a difficult time with balance." The report further described Mr. Brehm as " * * * very withdrawn while in the holding cell. He was sweating, holding his head between his legs, rocking back and forth. He also was [observed] mumbling and sticking his finger down his throat."

Mr. Brehm was later taken to a local hospital for treatment, and a warrant was issued for his arrest. Pursuant to a search warrant which was subsequently executed at the Brehm residence, police found, among other things, .380 caliber ammunition, a water pipe, and plastic jugs with rubber tubes attached. Following his release from the hospital, Robert Brehm was processed at the Pennridge Police Department. At that time, he advised the police to be careful with the jugs taken during the search

warrant because he didn't know what they contained, and the jugs were a part of what Mr. Brehm described to police as his "old meth lab."

According to the investigative file, on September 11, 2000, Mr. Brehm was arraigned in Pennsylvania state court on charges of aggravated assault; simple assault; recklessly endangering another person; terroristic threats; possessing an instrument of crime; and, possession with intent to use drug paraphernalia. His \$25,000 bail was not initially posted, and Mr. Brehm was sent for detention to the Bucks County Prison, where he was placed under a severe suicide watch due to depression.

The investigative file also recounts the Philadelphia Division receiving information from a detective in nearby Perkasie (Pennsylvania) that Mr. Brehm, then 19 years of age, had been arrested by Perkasie Police Department on possession of marijuana charges. The arresting officer is quoted by a DEA diversion investigator as saying that Mr. Brehm had been at a house where " * * * just about every drug imaginable was in the house." There is no information in the investigative file on the disposition of these charges against Mr. Brehm.

The investigative file further recounts that shortly after his arrest, Mr. Brehm's bail was paid by his mother. Later that same night, Mr. Brehm, who was driving his mother's car, hit a parked truck and then veered the vehicle into a garage, where it hit two antique Harley Davidson motorcycles. Mr. Brehm was the only person involved in the accident and was apparently unhurt. Nevertheless, he was subsequently arrested by local police, charged with misdemeanor offenses, and released the same night.

The investigative file further reveals that on September 6, 2000, the Philadelphia Division received information from the Pennsylvania Department of Health (Department of Health), advising that a complaint had been received from a manufacturer of medical gases located in Allentown, Pennsylvania. The complaint alleged that Mr. Brehm was "stockpiling nitrous oxide." DEA learned that Mr. Brehm was not licensed as a distributor by Department of Health to engage in this activity. DEA also received information that between March 31 and August 18, 2000, Mr. Brehm made ten purchases of nitrous oxide totaling \$2,474.32, as well as medical oxygen at a cost of \$28.54.

According to the investigative file, on October 16, 2000, the Philadelphia Division learned that Mr. Brehm attempted to place an order for some unspecified product with the Colorado

drug manufacturer, again, purportedly on behalf of Dr. Nichamin. In his faxed order, Mr. Brehm also left instructions with the drug manufacturer to deliver the ordered product to his residential address and Mr. Brehm provided the name of an individual who would accept the order on behalf of Dr. Nichamin. It turned out that the name of the individual left by Mr. Brehm to accept the order was same as the Bucks County Assistant District Attorney whose name was listed on the search warrant served at the Brehm residence in September of 2000. A copy of the warrant had been left at the premises at the time it was executed.

The investigative file further reveals that in a Bucks County court proceeding on March 13, 2001, Mr. Brehm waived a jury trial and entered a plea of not guilty due to mental health reasons, to charges arising from the assault on his father. The docket of that proceeding showed that on that same date, the presiding judge found Mr. Brehm not guilty on all counts, and under the state Mental Health Act, committed Mr. Brehm to mental health evaluation, to be reviewed yearly. As part of the judge's order, Mr. Brehm was to report to the Lenape Valley Foundation on March 16, 2001. It appears from the investigative file that on April 2, 2001, a subsequent court order was entered pursuant to Section 304(g) of the state Mental Health Procedures Act, committing Mr. Brehm to a partial hospitalization program at the Penn Foundation for up to one year.

The investigative file further describes the issuance of an unspecified order dated July 6, 2001, ordering Mr. Brehm to take medication as directed by his doctors and a subsequent request by the state that Mr. Brehm be held in contempt for failure to comply with Penn Foundation treatment recommendations as ordered by the court. The investigative file further describes a court finding that Mr. Brehm was in contempt of an earlier commitment order of the court, and on April 5, 2002, was recommitted to the partial program at the Penn Foundation for a period of up to one year, apparently for further observation.

The Deputy Administrator may deny an application under 21 U.S.C. 823(b) and (e), if she determines that the registration would be inconsistent with the public interest. *Associated Pharmaceutical Group, Ins.*, 58 FR 58181 (1993).

Pursuant to 21 U.S.C. 823(b) and (e), [i]n determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular

controlled substances into other than legitimate medical, scientific and industrial channels;

(2) Compliance with applicable State and local law;

(3) Prior conviction record of the applicant under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances;

(4) Past experience in the distribution of controlled substances;

(5) Such other factors as may be relevant to and consistent with the public health or safety.”

It is well established that these factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See *Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

Of the stated factors, the Deputy Administrator finds that there is no evidence in the investigative file that Mr. Brehm or his company is licensed under the State of Pennsylvania to handle controlled substances, or that his company was not in compliance with applicable state law, as contemplated by factor two. In addition, there is not evidence in the record that Mr. Brehm or his company have ever been convicted under controlled substance laws, or ever actually distributed controlled substances, as described under factors three and four. Accordingly, the Deputy Administrator finds factors one and five relevant to this proceeding.

It is clear that granting the application for DEA Certificate of Registration of Mr. Brehm d/b/a Infinite Pills would be inconsistent with the public interest. Under the first factor, maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels, the Deputy Administrator finds this factor relevant to the findings of DEA's investigation that Mr. Brehm had not developed a record keeping or invoicing system for his proposed business.

Factor one is further relevant to Mr. Brehm's attempts at obtaining various controlled substances from a drug manufacturer under the name and DEA registration of a physician without the latter's knowledge. Given the dishonest methods employed to obtain these drugs, the Deputy Administrator is left to conclude that Mr. Brehm's actions were an attempt to divert controlled substances to his personal use.

Therefore, the maintenance of effective

controls as contemplated under factor one, are not present with respect to Mr. Brehm's pending application for registration, and support the denial of his pending application.

With regard to factor five, such other factors as may be relevant to and consistent with the public health or safety, Mr. Brehm's proposed registered location is a residential townhouse which he shares with his mother and other family members. At the time of the submission of his application, Mr. Brehm was a 20-year old with no known experience working with controlled substances. He had no potential customers, nor had he made any visible efforts to establish a customer base.

Factor five is further relevant to Mr. Brehm's use of several artifices to obtain controlled substances from a Colorado drug manufacturer, including the unauthorized use of the name and DEA number of a physician; his apparent attempt to disguise his accent; his apparent misrepresentation to the drug company representative that he and the physician were roommates; and his apparent unauthorized use of the name of yet another individual as the contact person for delivery of controlled substances. In addition, Mr. Brehm attempted to have a physician's DEA number transferred to a different address, without the knowledge or authorization of the physician. This factor is also relevant to Mr. Brehm's fraudulent submission to a drug manufacturer of unsigned DEA order forms in a further attempt to obtain various controlled substances.

Also given consideration under factor five is the reference in the investigative file to an altercation involving Mr. Brehm and his father, resulting in the firing of a loaded weapon by Mr. Brehm. This altercation took place at the same address proposed by Mr. Brehm as a DEA registered location. Mr. Brehm was later charged with various assault, weapon, and drug charges. Following his arrest, and the execution of a search warrant at his residential address, Mr. Brehm advised law enforcement officers to exercise care in their handling of certain materials at the residence because they were part of a methamphetamine lab. The DEA investigative file also recounts the arrest of Mr. Brehm on a charge of possessing marijuana.

In addition to his legal woes, Mr. Brehm has exhibited behavior which can best be described as unstable. Such conduct raises further questions about his ability to adequately discharge the responsibilities of a DEA registrant.

Following his arrest in September of 2000, Mr. Brehm was placed under a

suicide watch after exhibiting erratic behavior while in custody. Following his release from police custody, the automobile in which he was driving struck three parked vehicles, and he was later charged with a misdemeanor offense apparently related to the incident. Pursuant to a subsequent court order, Mr. Brehm was committed to an institution for a mental health evaluation, and was found to be in violation of the court's order for noncompliance. Mr. Brehm's failure to comply resulted in his being recommitted for further mental health evaluation. Finally, DEA received information from the Pennsylvania Department of Health which alleged that Mr. Brehm stockpiled nitrous oxide without state authorization to do so.

It is clear that Mr. Brehm and the firm that he represents, does not possess the requisite qualifications for DEA registration as a distributor. Moreover, in reviewing the instant request for DEA registration, and in light of Mr. Brehm's failure to request a hearing in this matter, the Deputy Administrator has only the benefit of the DEA investigative file in making her determination. No evidence has been submitted on behalf of the applicant in support of his pending application. Based on the above, the Deputy Administrator reiterates that the applicant's registration would be inconsistent with the public interest and therefore, his application for registration must be denied.

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), hereby orders that the application for DEA Certificate of Registration as a distributor submitted by Robert Brehm d/b/a Infinite Pills, be, and it hereby is, denied. This order is effective August 5, 2004.

Dated: June 21, 2004.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03-51]

Miles J. Jones, M.D.; Revocation of Registration

On August 11, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order