

System Manager, and be clearly marked "Privacy Act Access Request." The request should include the component where the records reside, if known (generally, the employing component), and must include the requestor's name, title, organization, address, phone number and a general description and purpose of records sought, and must include the requestor's full name, current address, and date and place of birth. The request must be signed and dated and either notarized or submitted under penalty of perjury. Records will be released in accordance with the Freedom of Information Act, as well as the Privacy Act.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request to the System Manager listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Please include the information requested in "Record Access Procedures" above.

RECORD SOURCE CATEGORIES:

Sources of information include employees who make written requests for application to the leave sharing programs, including supporting documentation, such as time and attendance records and medical records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03-20]

William E. "Bill" Smith d/b/a B & B Wholesale; Denial of Application

On March 31, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to B & B Wholesale (Respondent), proposing to deny its application executed on May 21, 2002, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of the Respondent 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 was delivered to the Respondent by certified

mail, and the Respondent timely requested a hearing under the business name "William "B" Smith d/b/a B & B Wholesale." On April 25, 2003, the presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued an Order for Prehearing Statements, directing the Respondent to file a prehearing statement no later than June 9, 2003. However, the Respondent did not file a prehearing statement as directed. In her June 26, 2002, Order Terminating Proceedings, Judge Bittner deemed the Respondent as having waived its right to a hearing in the matter. Following the termination of proceedings, Judge Bittner transmitted the matter to the Deputy Administrator for issuance of a final order.

In light of the above, the Acting Deputy Administrator similarly finds that the Respondent has waived its hearing right. *Aqui Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53(c) and (d) and 1316.67 (2003).

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.

Phenylpropanolamine, also a list I chemical, is presently 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. Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is an ongoing public health concern in the United States.

The Acting Deputy Administrator's review of the investigative file reveals that DEA received an application dated May 21, 2002, from the Respondent located in Huntingdon, Tennessee. The application was submitted on behalf of the Respondent by its owner, Bill Smith (Mr. Smith). The Respondent seeks DEA registration as a distributor of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. There is no evidence in the investigative file that the Respondent has sought to modify its pending registration application in any respect.

On August 1, 2002, a DEA Diversion Investigator conducted a pre-registration inspection of the Respondent's premises, where he met with Mr. Smith. During the inspection, the Diversion Investigator advised Mr. Smith of regulatory requirements and problems surrounding the diversion of list I chemicals. The Diversion Investigator also reviewed security, recordkeeping and distribution procedures with Mr. Smith and provided him with appropriate materials regarding DEA requirements for handlers of listed chemicals.

Mr. Smith stated that he is sole owner and the only employee of his company. DEA's investigation revealed that the Respondent is a distributor of general merchandise, and distributes a variety of items including gloves, lighters, novelty items, sundry items and a variety of other merchandise. The company is located in a predominantly residential area at Mr. Smith's residence, and sells various items that would be carried in a convenience store.

Mr. Smith further disclosed that he previously owned Bill's Bait and Tackle in Huntingdon, Tennessee, a business he owned and operated for approximately twenty-five years. According to Mr. Smith, Bill's Bait and Tackle sold a variety of fishing and tackle items and also sold list I chemical products. Following the dissolution of that business, Mr. Smith started B&B Wholesale in May 2002. The DEA investigative file reveals that an application for an unspecified DEA registration was filed on behalf of Bill's Bait and Tackle by Bill Smith, however, that application was withdrawn in January 1999.

Mr. Smith further stated that approximately five to ten percent of his business would be devoted to the sale of list I chemical products. Among the list I products that Mr. Smith planned for distribution were brand names such as Mini Thins, Max Brand, Tylenol Cold and Sinus, Tylenol Allergy and Sinus, Vicks NyQuil Liquitabs, Alka Seltzer Plus, Cold, Actifed, Sudafed and Advil Cold and Sinus. Mr. Smith added that he would limit the amount of Mini Thin and Max Alert products specifically in stock to 288 bottles.

When asked about potential suppliers of listed chemicals to his company, Mr. Smith informed DEA personnel that he planned to purchase these products from a company located in East, Lexington, Tennessee. In an unrelated investigation of that company, DEA found that the company supplied its listed chemical products primarily to convenience stores and gas stations. That investigation further revealed that

the company's own suppliers have been identified as companies whose products have been seized from clandestine methamphetamine labs, and the company was unable to account for quantities of listed chemicals it bought and sold.

With respect to potential customers, Mr. Smith stated that he has approximately forty to fifty customers, which are primarily convenience stores and gas stations. Of that number, approximately thirty-five customers planned on purchasing list I chemical products from the Respondent. Mr. Smith also stated that he verifies and identifies a customer by physically going to the site. Mr. Smith further explained that his customer base range is within 100 miles of Huntingdon, Tennessee and his customers have told him that when he received his DEA Registration Certificate, they would only buy list I chemical products from the Respondent.

DEA's investigation further revealed that the Respondent's proposed storage area for listed chemicals is the front cab of a Ford Ranger truck. Mr. Smith told the DEA that list I chemical products would be stored in the front of the cab only and would be stored only from the time that he picked them up on Wednesday morning to the time they were delivered on the same day. Mr. Smith further stated that the doors to the truck remained locked when the vehicle was not occupied, and the truck contains an electronic burglar alarm that emits an audible sound when activated. When not in use, the truck is parked outdoors in a driveway.

Pursuant to 21 U.S.C. 823(h), the Acting Deputy Administrator may deny an application for Certificate of Registration if she determines that granting the registration would be inconsistent with the public interest as determined under that section. Section 823(h) requires the following factors be considered in determining the public interest:

(1) Maintenance of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) Compliance with applicable Federal, State, and local law;

(3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) Any past experience in the manufacture and distribution of chemicals; and

(5) Such other factors as are relevant to and consistent with the public health and safety.

As with the public interest analysis for practitioners and pharmacies

pursuant to subsection (f) of section 823, these factors are to be considered in the disjunctive: the Acting Deputy Administrator may rely on any one or combination of factors, and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See, e.g., Energy Outlet*, 64 FR 14269 (1999). *See also Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

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

With regard to factor one, maintenance of effective controls against diversion of listed chemicals into other than legitimate channels, the DEA pre-registration inspection documented inadequate security at the proposed registered location of the Respondent. Mr. Smith has proposed the storage of listed chemical products inside of a pickup truck which is routinely parked in an outside driveway. Despite Mr. Smith assurances that he can safely secure these products, the Acting Deputy Administrator finds the prospect of listed chemicals being stored in an unattended vehicle as fraught with the dangers of diversion. Therefore, this factor weighs against the granting of the respondent's pending registration application.

With respect to factor four, the applicant's past experience in the distribution of chemicals, the Acting Deputy Administrator finds this factor relevant to Mr. Smith's apparent lack of experience in the handling of list I chemical products. The DEA investigative file shows that the Respondent is a retailer of general merchandise and before that, Mr. Smith operated a bait and tackle concern. Mr. Smith's past history as an entrepreneur suggests that he has not had any experience in handling listed chemical products. In prior DEA decisions, such a lack of experience in the handling list I chemicals was a factor in a determination to deny a pending application for DEA registration. *See, Matthew D. Graham*, 67 FR 10229 (2002); *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002). Therefore, this factor similarly weights against the granting of the Respondent's pending application.

With respect to factor five, other factors relevant to and consistent with the public safety, the Acting Deputy Administrator finds this factor relevant to the Respondent's proposal to distribute listed chemical products primarily to convenience stores and gas stations. While there are no specific prohibitions under the Controlled

Substance Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found that business establishments such as gas stations and convenience stores constitute sources for the diversion of listed chemical products. *See, e.g., Sinbad Distributing*, 67 FR 10232, 10233 (2002); *K.V.M. Enterprises*, 67 FR 70968 (2002) (denial of application based in part upon information developed by DEA that the applicant proposed to sell listed chemicals to gas stations, and the fact that these establishments in turn have sold listed chemical products to individuals engaged in the illicit manufacture of methamphetamine); *Xtreme Enterprises, Inc.*, *supra*.

On a related note, factor five is relevant to the distribution practices of the Respondent's proposed supplier of listed chemicals which have resulted in the diversion of these products. The Acting Deputy Administrator also finds this factor relevant to the stated intentions of some of the Respondent's customers who have expressed the desire to purchase only listed chemicals products from the Respondent, despite the latter's sale of various other products.

As noted above, there is no evidence in the investigative file that the Respondent has sought to modify its pending application with regard to listed chemical products it seeks to distribute. Among the listed chemical products the Respondent intends to distribute is phenylpropanolamine. In light of this development, the Acting Deputy Administrator also finds factor five relevant to the Respondent'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. *Shani Distributors*, *supra*. Based on the foregoing, the Acting Deputy Administrator concludes that granting the pending application of the Respondent would be inconsistent with the public interest.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, previously submitted by William E. "Bill" d/b/a B&B Wholesale be, and it hereby is, denied. This order is effective May 26, 2004.

Dated: March 29, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Gazaly Trading; Denial of Application

On March 14, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Gazaly Trading (Gazaly) proposing to deny its application executed on November 9, 2000, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of Gazaly 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 Gazaly that should no 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 Gazaly at its proposed registered location and was received on March 24, 2003. DEA has not received a request for hearing or any other reply from Gazaly or anyone purporting to represent the company in this matter.

Therefore, the Acting Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause to the applicant's last known address, and (2) no request for hearing having been received, concludes that Gazaly has waived its hearing right. *See Aqui Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53 (c) and (d) and 1316.67 (2003). The Acting Deputy Administrator finds as follows:

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance.

Phenylpropanolamine, also a list I chemical, is presently 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. Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is an ongoing public health concern in the United States.

The Acting Deputy Administrator's review of the investigative file reveals that DEA received an application dated November 9, 2000, from Gazaly Trading located in Orlando, Florida. The application was submitted on behalf of Gazaly by its owner, Redwan Gazaly (Mr. Gazaly). Gazaly seeks DEA registration as a distributor of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. There is no evidence in the investigative file that Gazaly has sought to modify its pending registration application in any respect.

Following receipt of the above application, on December 28, 2000, DEA Diversion Investigators conducted an on-site pre-registration inspection at Gazaly's proposed registered location. During the inspection, Diversion Investigators advised Mr. Gazaly of regulatory requirements and problems surrounding the diversion of list I chemicals. The Diversion Investigators also reviewed security, recordkeeping and distribution procedures with Mr. Gazaly and provided him with appropriate materials regarding DEA requirements for handlers of listed chemicals.

During the pre-registration investigation, Mr. Gazaly informed DEA Diversion Investigators that he had no previous experience handling list I chemical products. Nevertheless, he anticipated that Gazaly's sale of those products would constitute approximately 10% of his business activity. Mr. Gazaly also further disclosed that his customers are convenience stores, gas stations, and general stores, and the purpose of obtaining a registration to distribute list I chemical was to ensure distribution of other products to his customers.

Mr. Gazaly also provided DEA a list of customers to whom listed chemical products would be sold. Upon review of the list it was learned that approximately fifteen potential customers of Gazaly were associated with criminal targets in previous DEA investigations. Several of Gazaly's potential customers were also targets of ongoing criminal cases, apparently related to unlawful handling of listed chemical products. In addition, Mr. Gazaly advised DEA Diversion

Investigators that he would only distribute list I chemicals to customers located in the State of Florida; however, further review of the customer list revealed a business establishment located outside of Florida that was also the target of a DEA criminal investigation.

Pursuant to 21 U.S.C. 823(h), the Acting Deputy Administrator may deny an application for Certificate of Registration if she determines that granting the registration would be inconsistent with the public interest as determined under that section. Section 823(h) requires the following factors be considered in determining the public interest:

- (1) Maintenance of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) Compliance with applicable Federal, State, and local law;
- (3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) Any past experience in the manufacture and distribution of chemicals; and
- (5) Such other factors as are relevant to and consistent with the public health and safety.

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, these factors are to be considered in the disjunctive; the Acting Deputy Administrator may rely on any one or combination of factors, and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See, e.g., Energy Outlet*, 64 FR 14269 (1999). *See also Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

The Acting Deputy Administrator finds factors four and five relevant to Gazaly's pending registration application.

With respect to factor four, the applicant's past experience in the distribution of chemicals, the Acting Deputy Administrator finds this factor relevant to Mr. Gazaly's lack of experience in the handling of list I chemical products. In prior DEA decisions, the lack of experience in the handling list I chemicals was a factor in a determination to deny a pending application for DEA registration. *See, Matthew D. Graham*, 67 FR 10229 (2002); *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002). Therefore, this factor similarly weighs against the granting of Gazaly's pending application.

With respect to factor five, other factors relevant to and consistent with