DEPARTMENT OF JUSTICE

Drug Enforcement Administration

John E. McCrae d/b/a J & H Wholesale; Denial of Application

On December 8, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to John E. McCrae d/b/a J & H (J & H) prosing to deny its application executed on April 29, 2003, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of J & H would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h) and 824(a). The Order to Show Cause also notified J & H 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 J & H at its address of record in Middleburg, Florida and was received on behalf of the firm on December 16, 2003. Nevertheless, DEA has not received a request for hearing or any other reply from J & H, or anyone purporting to represent the company 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 to the applicant's address of record, and (2) not request for hearing having been received, concludes that J & H has waived its hearing right. *See* Aqui Enterprises, 67 FR 12576 (2002). After considering relevant material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53(c) and (d) and 1316.67 (2003). The 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). Psedoephedrine 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 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 Deputy Administrator's review of the investigative file reveals that by application dated April 29, 2003, J & H sought DEA registration as a distributor of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The application was submitted on behalf of J & H by its owner, John E. McCrae (Mr. McRae). There is no evidence in the investigative file that J & H has sought to modify its pending application in any respect.

According to the investigative file, on July 11, 2003, a DEA diversion investigator contacted Mr. McRae regarding J & H's pending application. It is not clear from the investigative file whether the July 11 contact was made in person or over the telephone. The diversion investigator advised Mr. McRae that DEA would need to review a list of his company's potential customers, products, and suppliers of list I chemicals. Mr. McRae was informed that list I chemicals are regulated by DEA because they have been used in the illicit manufacture of methamphetamine and other controlled substances.

Mr. McRae at one point inquired with DEA investigators about the timing of any approval of his company's pending registration application. He stated that he had been approached by customers seeking to purchase list I chemical products from him, and further added that he could ''double [his] sales tomorrow'' if his application was approved. DEA learned that Mr. McRae has no prior experience handling over-the-counter medications, including list I chemical products.

On August 6, 2003, two DEA diversion investigators conducted an on-site pre-registration inspection at J & H's proposed registered location. The location requested by J & H as a proposed DEA registered address was Mr. McRae's home residence. DEA's inspection revealed that Mr. McRae sells approximately 150 novelty and general merchandise items to customers located in various Florida cities, including Jacksonville and Gainsville. Mr. McRae estimated that the sale of list I chemical products would constitute approximately ten percent or less of his company's total sales.

Mr. McRae then provided to DEA personnel a list of customers to whom listed chemical products would be sold. The customer list was comprised primarily of convenience and beverage stores, as well as gas stations. Mr. McRae stated that he began selling novelty items to convenience stores on a full time basis in March 2003. When asked about the manner in which he identified his customers, Mr. McRae explained that he makes site visits to his customers' stores and knows them from prior transactions. He further stated that on most occasions, he deals with the owner of a particular establishment and only accepts cash payment, which usually comes directly from the customers' cash register. Only occasionally has Mr. McRae accepted a business check in payment for a sale and he never accepts personal checks.

As noted above, J & H is located at Mr. McRae's residential home. With respect to security of the premises, DEA investigators found that the home had a residential alarm system. DEA's inspection further revealed that the only security devices were contact switches on the home's front and patio doors and there was no motion detector on the premises because of the family canine.

With respect to storage of listed chemical products, DEA personnel were informed that these products would be stored in a plastic tote bin maintained in the garage of the residence. When DEA investigators arrived at the residence, they noted that an exterior garage door was open and a young male friend of Mr. McRae's son entered the home through the interior garage door. Family members and the visitor were later seen using the garage's interior door to depart the home.

Pursuant to 21 U.S.C. 823(h), the 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 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 Deputy Administrator finds factors one, four and five relevant to J & H'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 J & H. Mr. McRae proposes to store listed chemical products in the garage of his residential location. However, DEA investigators documented a residential alarm system in which the only security devices are contact switches on the front and patio doors of the residence. Additionally, the garage where listed chemicals are to be stored has an exterior overhead door which appears to be easily accessed, and the interior garage door appears to be a common passage way into and out of the residential home for Mr. McRae's family members and their friends.

With regard to factor two, compliance with applicable Federal, State, and local law, there is no evidence before the Deputy Administrator that J & H has failed to comply in any respect with such laws.

With respect to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant to Mr. McRae's lack of experience in handling of list I chemical products. In prior DEA decisions to deny pending applications 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 J & H's pending application.

With respect to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor relevant to J & H's proposal to distribute listed chemical products from a residential location to customers comprised primarily of 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 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 Enterprise, Inc., *supra.*

In the instant matter, the Deputy Administrator finds curious the product specific inquiries of J & H's customers with respect to the applicant's sale of list I chemical products. The Deputy Administrator is also intrigued by Mr. McRae's reliance on the marketing of these products to ''double'' his overall sales totals when his own projections regarding these products were approximately ten percent or less of total sales.

The high priority placed upon the proposed sale of listed chemical products by J & H to convenience stores and gas stations, in conjunction with the specific requests by these entities to obtain listed chemical products for sale appears to defy current data regarding the marketing and sale of these products. DEA has previously accepted expert analysis of sales data regarding listed chemical products where it was found that establishments such as convenience stores and gas stations ''have a very small or no likelihood of selling [listed chemical] products over the counter to consumers seeking remedies for nasal congestion from allergies, colds or other conditions.'' *See,* Branex, Incorporated, 69 FR 8682, 8690–92 (2004). Consistent with the ruling in Branex, the Deputy Administrator concludes here that the scale of J & H's proposed sale of list I chemical products to its customers appears not in keeping with the normal chain of distribution for goods of this kind.

As noted above, there is no evidence in the investigative file that J & H ever sought to modify its pending application with respect to the listed chemical products it seeks to distribute. Among the listed chemical products the firm seeks to distribute is phenylpropanolamine. In keeping with prior DEA rulings, the Deputy Administrator also finds factor five relevant to J & H'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, 68 FR 62324 (2003). Based on the foregoing, and the lack of evidence by the applicant to the contrary, the Deputy Administrator concludes that granting the pending application of J & H 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 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, previously submitted by John E. McRae d/b/a J & H Wholesale be, and it hereby is, denied. This order is effective September 20, 2004.

Dated: July 27, 2004.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Proveedora Jiron, Inc. Edilberto Jiron, President; Denial of Application

On October 30, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Proveedora Jiron, Incorporated, Edilberto Jiron, President (Proveedora) proposing to deny its application, executed on March 25, 2003, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged in relevant part that granting the application of Proveedora 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 Proveedora 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 Edilberto Jiron (Mr. Jiron), President of Proveedora at his firm's proposed registered location in Miami, Florida. A return receipt, which was part of the investigative file, indicates that the show cause order was received on November 12, 2003, on behalf of Proveedora. DEA has not received a request for hearing or any other reply from Proveedora or anyone purporting to represent the company in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since receipt of the Order to Show Cause, and (2) no request for hearing having been received, concludes that Proveedora has waived its hearing