DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 02–26]

J&P Distributor; Denial of Application

On December 28, 2001, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to J&P Distributor (J&P), proposing to deny its application, executed on November 15, 2000, for DEA Certificate of Registration as a distributor of the list I chemical ephedrine. Prior to the issuance of the show cause order, J & P requested modification of its application to include psuedoephedrine, also a list I chemical. The Order to Show Cause alleged that granting J & P's application would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h) and 824(a)(4).

The Order to Show Cause was delivered to J&P by certified mail, and the applicant timely requested a hearing. However, after the matter was docketed before Administrative Law Judge Mary Ellen Bittner (Judge Bittner), the Government filed a request for termination of proceedings on the ground that J&P withdrew its request for hearing. In her April 19, 2002, Order Terminating Proceedings, Judge Bitter similarly found that J&P had withdrawn its request for hearing and she subsequently terminated all proceedings before her. The matter was later transmitted to the Acting Deputy Administrator for issuance of a final order.

In light of the withdrawal of its request for hearing, the Acting Administrator finds that J&P has waived its hearing right. Aqui Enterprises, 67 FR 12576 (2002). After considering relevant material from the investigative file in this matter, the Acting Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46. The Acting 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) and 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals that are commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a growing problem in the United States.

The Acting Administrator's review of the investigative file reveals that in or around December 2000, an application dated November 15, 2000, was received by DEA on behalf of J&P. The applicant sought DEA registration as a distributor of the list I chemical ephedrine. On March 15, 2001, Pat Alexander, co-owner of J&P, submitted a written request to add pseudoephedrine to J&P's application. Because J&P did not submit its application for registration on or before July 12, 1997, the firm did not qualify for temporary exemption from the requirement of registration, pursuant to 21 CFR 1309.10. Accordingly, J&P was not authorized to distribute listed chemicals prior to approval of its pending application for registration. See, Aseel, Incorporated, Wholesale Division, 66 FR 35459 (2001).

The Acting Administrator finds that J&P is a retail distributor located in Rockmart, Georgia, and is owned by Jeff Alexander and his wife Pat. The firm specializes in the sale of candy, hats, gloves and other novelty items. J&P was purchased from Mrs. Alexander's brother Larry Weaver under its former name, Novelty Plus. Novelty Plus was previously registered with DEA as a distributor of list I chemicals under Certificate of Registration number 002093NYY. That registration expired on October 31, 2000.

As part of a pre-registration investigation, DEA Diversion Investigators met with J&P's owners on March 15, 2001. J&P's owners informed DEA personnel that the firm anticipated that its retail sale of list I chemical products would constitute fifty-percent of the firm's business. J&P also provided to DEA investigators a list of ephedrine and pseudoephedrine products that it intended to sell, including ''Heads Up'' and ''Max Alert'' brands in 60-count bottles. A review of J&P's list of proposed customers reveals that they are comprised primarily of convenience stores or gas stations.

J&P also provided to DEA investigators the names of two of its proposed suppliers of list I chemical products. One of the suppliers, located in Belvedere, South Carolina, was previously the subject of DEA show cause proceedings to revoke its DEA registration, and was alleged to have violated DEA requirements related to recordkeeping, excessive purchases and failure to report suspicious orders of listed chemicals. In addition, as part of a December 2000 seizure of listed chemical products, law enforcement personnel in Springdale, Arizona seized approximately 51,000 pseudoephedrine tablets. It was subsequently determined that these products originated from J&P's proposed supplier.

During the month of July 2001, DEA conducted an unrelated regulatory investigation of J&P's second proposed supplier of listed chemicals, Galaxy Wholesale, Incorporated, of Mabletonton, Georgia. During an inspection of Galaxy Wholesale's distribution records, DEA investigators uncovered a sales invoice (with the purported signature of Pat Alexander) which revealed that on March 1, 2001, J&P purchased ''Heads Up'' ephedrine products (60-count bottles and 6-count packets) from Galaxy Wholesale. At the time of the purchase, J&P was not registered with DEA to handle listed chemicals. During the pre-registration inspection of March 15, 2001, neither Jeff or Pat Alexander informed DEA investigators of J&P's purchase of list I chemicals from Galaxy Wholesale when asked about their experience in handling list I chemicals products.

DEA's investigation further revealed that between December 2000 and March 2002, J&P sold to three retail establishments approximately 350 bottles (60-count) of various ephedrine products, as well as blister packets of other ephedrine and pseudoephedrine products. At the time of these sales, J&P's application for DEA registration was pending approval.

Pursuant to 21 U.S.C. 823(h), the Acting Administrator may deny an application for Certificate of Registration if he 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 Administrator may rely on any one or 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, e.g. Energy

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

The Acting Administrator finds factors two, four and five relevant to J & P's pending application.

With respect to factor two, the applicant's compliance with applicable law, the Acting Administrator finds that between December 2000 and March 2002, J&P violated applicable law by distributing, without a DEA registration, bottle quantities of ephedrine as well as pseudoephedrine products to three retail establishments, in violation of 21 U.S.C. 843(a)(9). The Acting Administrator also finds factor two relevant to J&P's March 2001 purchase of ephedrine products from Galaxy Wholesale while not registered with DEA, in violation of 21 U.S.C. 822(a) and 21 CFR 1309.21(a) and 1310.09.

With respect to factor four, the applicant's past experience in the distribution of chemicals, the Acting Administrator finds that notwithstanding the above referenced purchase and sale of listed chemical products by the owners of J&P, the applicant has not demonstrated that it possesses any meaningful experience in the distribution of these products. The Acting Administrator finds J&P's lack of experience most telling in the fact that its owners continued the purchase and sale of listed chemical products even as its application for registration was being reviewed by DEA. This factor weighs against the granting of Respondent's pending application. See, CHM Wholesale Co., 67 FR 9985 (2002); Hologram Wonders, Inc., 67 FR 10231 (2002); Southern Illinois Wholesale, Inc., 67 FR 12583 (2002).

J&P's continued sale and purchase of listed chemical products during the pendency of its registration application is also relevant to factor five, other factors relevant to and consistent with the public safety. The Acting Administrator also finds factor five relevant to the failure on the part of J&P's owners to inform DEA investigators of any previous experience handling listed chemicals, when the firm in fact purchased ephedrine products from Galaxy Wholesale.

The Acting Administrator also finds that J&P provided to DEA investigators a list of customers that are comprised solely of convenience stores and gas stations. While there are no specific prohibitions regarding the sale of listed chemicals products to these entities, DEA has nevertheless found on previous occasions 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 Enterprises, Inc., 67 FR 76195 (2002).

Factor five is further relevant to J&P's proposed use of listed chemical supplier that previously was the subject of DEA show cause proceedings. The show cause proceedings were based on allegations that the supplier violated laws and regulations related to its DEA registration, and engaged in distribution practices that led to the diversion of listed chemicals.

In light of the above, the Acting Administrator concludes that it would be inconsistent with the public interest to grant the application of J&P Distributor.

Accordingly, the Acting 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) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, previously submitted by J&P Distributor be, and it hereby is, denied. This order is effective August 25, 2003.

Dated: July 3, 2003.

William B. Simpkins,

Acting Administrator.

[FR Doc. 03–18869 Filed 7–23–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Sustances; Notice of Registration

By Notice dated March 11, 2003, and published in the **Federal Register** on April 2, 2003, (68 FR 16091), Penick Corporation, 158 Mount Olivet Avenue, Newark, New Jersey 07114, made application by renewal to the Drug Enfocement Adminstration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Cocaine (9041)	II
Ecgonine (9180)	II

The above cited Notice contained an error in that the drug code for Cocaine was listed as 9040 rather than 9041.

The firm plans to manufacture the listed controlled substances for the manufacture of a non-controlled substance flavor extract.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Penick Corporation to manufacture the listed contolled substances is consistent with the public interest at this time. DEA has investigated Penick Corporation to ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed is granted.

Dated: July 18, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–18867 Filed 7–23–03; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 25, 2001, the University of Massachusetts, Lyle E. Craker, Professor, Department of Plant and Soil Science, Stockbridge Hall, Box 37245, Amherst, Massachusetts 01003, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of Marijuana (7360) and Tetrahydrocannabinols (7370), basic classes of Schedule I controlled substances.

The University of Massachusetts-Amherst plans to bulk manufacture (cultivate) Marijuana and Tetrahydrocannabinols for distribution to approved researchers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to this notice of application.