

consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Abbott Laboratories on a regular basis to ensure that the company's continued registration is consistent with the public interest. This investigation 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 section 1008(a) of the Controlled Substances Import and Export Act and in accordance with Title 21, Code of Federal Regulations, § 1301.34, the above firm is granted registration as an importer of the basic class of controlled substance listed above.

Dated: March 3, 2004.

William J. Walker,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

ANM Wholesale; Denial of Application

On February 28, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to ANM Wholesale (ANM) proposing to deny its application executed on January 9, 2001, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of ANM 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 ANM 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 ANM at its proposed registered location in Tampa, Florida and was received on March 15, 2003. DEA has not received a request for hearing or any other reply from ANM 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 a hearing having been

received, concludes that ANM 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 in or around early 2001, an application dated January 9, 2001, was received by DEA on behalf of ANM located in Tampa, Florida. The application was submitted on behalf of ANM by its owner, Mohamed A. Fawaz (Mr. Fawaz). ANM sought DEA registration as a distributor of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. There is no evidence in the investigative file that ANM has sought to modify its pending application in any respect.

Following receipt of the above application, on April 25, 2001, DEA diversion investigators conducted an on-site pre-registration inspection at ANM's proposed registered location. The location requested by ANM for DEA registration was Mr. Fawaz's residence. Mr. Fawaz informed DEA investigators that since 2000, ANM's primary business was selling cigars, cigarettes and over-the-counter items to gas stations located throughout Hillsborough and Polk counties in Florida. These items were sold out of Mr. Fawaz's residence. During the inspection, investigators advised Mr. Fawaz of regulatory requirements and problems surrounding the diversion of list I chemicals. The investigators also reviewed security, recordkeeping and

distribution procedures with Mr. Fawaz, and provided him with appropriate materials regarding DEA requirements for handlers of listed chemicals.

With regard to its anticipated sale of listed chemical products, Mr. Fawaz estimated that ANM's annual sales involving list I chemicals would be approximately 1% of the firm's total sales. Mr. Fawaz stated that ANM's customers were primarily located within a thirty mile area of Tampa, and he then provided DEA investigators with a list of twenty-seven customers who purchased cigars, cigarettes and over-the-counter items from ANM. The customer list was comprised primarily of gas stations and convenience stores. According to the investigative file, Mr. Fawaz further disclosed that he had no prior experience in the sale or marketing of over-the-counter medications that contain list I chemicals, and he was unfamiliar with the milligram strengths of the listed chemical products that he planned to sell.

A DEA investigator then inquired with the State of Florida, Planning and Growth Management/Permit and Zoning Department (the Zoning Department) for Hillsborough County to determine whether Mr. Fawaz's operation of a business at a residential location was in compliance with state zoning requirements. DEA was informed by a representative of the Zoning Department that Mr. Fawaz's residence was located in a "Residential Area Only Zone" and not in a "Commercial Zone Area" of Hillsborough County. Therefore, ANM was not in compliance with the zoning laws for Hillsborough County.

After receiving the above information, a DEA investigator advised Mr. Fawaz of the need to obtain zoning authorization for his business. DEA subsequently learned that Mr. Fawaz contacted the Zoning Department where he disclosed his plan to keep list I chemical products stored in his vehicle at an undisclosed location. The Zoning Department then informed Mr. Fawaz that he could apply for a rezoning permit for his place of residence; however Mr. Fawaz declined to submit the application.

DEA subsequently informed Mr. Fawaz that based on the latter's expressed plan to store listed chemical products in an automobile, it was unlikely that ANM's application for registration would be approved, since storage of such products in this manner would not be in compliance with DEA security and controlled premise requirements. Mr. Fawaz was further reminded of the Florida zoning requirements for his business. Mr. Fawaz then informed DEA investigators that he declined the opportunity to

apply for a rezoning permit because he did not think an application would be approved. He further expressed the desire not to relocate his business or his occupational license from his residence.

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, two, four and five relevant to ANM'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 ANM. Mr. Fawaz proposed initially to store listed chemical products at his residential location. However, when he discovered that his residential location did not comply with local zoning laws, Mr. Fawaz then proposed storing listed chemicals in a vehicle.

With regard to factor two, compliance with applicable Federal, State, and local law, the Acting Deputy Administrator notes that Florida state and county law requires zoning approval for the operation of a particular business in areas known as "Commercial Zones."

As of the date of DEA's inspection, the Zoning Department had not approved ANM for a permit because of the firm's location in a residential area. Mr. Fawaz does not own a zoning permit for his business, and at the time of DEA's investigation, he had no intention of obtaining one. The failure to obtain a proper zoning permit for business purposes has been cited under factor two as a basis for the denial of an application for DEA registration to distribute list I chemicals. *See, Daniel E. Epps, Jr.*, 67 FR 9987 (2002).

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. Fawaz'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 ANM's pending application. In addition, the Acting Deputy Administrator finds factor four relevant to Ms. Fawaz's apparent unfamiliarity with listed chemical products, as evidenced by his lack of knowledge regarding the milligram strengths of the listed chemical products that he planned to sell.

With respect to factor five, other factors relevant to and consistent with the public safety, the Acting Deputy Administrator finds this factor relevant to ANM'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 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*.

As noted above, there is no evidence in the investigative file that ANM ever sought to modify its pending application with respect to listed chemical products it seeks to distribute.

Among the listed chemical products that the firm seeks to distribute is phenylpropanolamine. In light of this development, the Acting Deputy Administrator also finds factor five relevant to ANM'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 for an application for registration. *Shani Distributors*, 68 FR 62324 (2003). Based on the foregoing, the Acting Deputy Administrator concludes that granting the pending application of ANM 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 ANM Wholesale be, and it hereby is, denied. This order is effective April 12, 2004.

Dated: February 20, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated September 17, 2003, and published in the **Federal Register** on October 7, 2003, (68 FR 57928), Cayman Chemical Company, 1180 East Ellsworth Road, Ann Arbor, Michigan 48108, made application by renewal to the Drug Enforcement Administration for registration as a bulk manufacturer of the basic classes of controlled substances listed below.

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The firm plans to manufacture small quantities of marijuana derivatives for research purpose.

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 Cayman Chemical Company to manufacture the listed controlled substance is consistent with