

chemicals while not registered with DEA, and by failing to keep and maintain required records concerning regulated transactions.

Accordingly, the 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 application for a DEA Certificate of Registration submitted by Paragon Associates be denied. This order is effective April 4, 2002.

Dated: February 22, 2002.

**Asa Hutchinson,**  
Administrator.

#### Certificate of Service

This is to certify that the undersigned, on February 25, 2002, placed a copy of the Final Order referenced in the enclosed letter in the interoffice mail addressed to Wayne Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, DC 20537; and caused a copy to be mailed, postage prepaid, registered return receipt to Mr. George Fan, Paragon Associates, 1300 John Reed Court, #13, City of Industry, California 91745.

Karen C. Grant.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Performance Construction, Inc.; Denial of Application

On or about December 6, 2000, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause (OTSC) by certified mail to Performance Construction, Inc. (Performance), located in Lakeland, Florida, notifying it of an opportunity to show cause as to why the DEA should not deny its application, dated June 30, 2000, for a DEA Certificate of Registration as a manufacturer of List I chemicals and deny any request to modify its application to distribute List I chemicals, pursuant to 21 U.S.C. 823(h), as being inconsistent with the public interest. The order also notified Performance that, should no request for hearing be filed within 30 days, the right to a hearing would be waived.

The OTSC was received December 11, 2000, as indicated by the signed postal receipt. Since that time, no further response has been received from the applicant nor any person purporting to represent the applicant. Therefore, the

Administrator of the DEA, finding that (1) thirty days having passed since receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Performance is deemed to have waived its right to a hearing. After considering relevant material from the investigative file in this matter, the Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Administrator finds that during a pre-registration inspection of Performance's premises on October 5, 2000, DEA investigators spoke with the president/owner of Performance, who stated that Performance was a general contractor, not engaged in the business of manufacturing, handling, or distribution of listed chemicals, nor did it have any knowledge or experience in this field. He further stated that Performance did not wish to manufacture listed chemicals, but proposed to be registered in order to make a one-time distribution of the List I chemical GBL to an individual also not engaged in the business of handling listed chemicals, purportedly for the purpose of stripping paint from a boat.

The Administrator notes that GBL (gamma-butyrolactone) has use as an industrial solvent. GBL is also a known precursor chemical, however, and is readily synthesized into the Schedule I controlled substance GHB. Schedule I controlled substances have no known medical uses, and are highly subject to abuse. 21 U.S.C. 812(b).

DEA investigators contacted numerous marine manufacturers and boat refinishers in south Florida; however none were aware of the use of GBL in the marine industry or for the proposed use in vessel paint stripping. In fact, none of those contacted by DEA had even heard of GBL.

The Administrator further notes that a long-standing DEA policy prohibits the granting of registrations that are essentially "shelf registrations," that is, registrations for which there is no intent to use. The granting of a registration for a one-time distribution of a chemical that is otherwise widely available from DEA registrants throughout the United States would be inconsistent with this long-standing DEA policy.

Pursuant to 21 U.S.C. 823(h), the Administrator may deny an application for a DEA Certificate of Registration if he determines that granting the registration would be inconsistent with the public interest. Section 823(h) requires the following factors be considered:

(1) Maintenance by the applicant of effective controls against diversion of

listed chemicals into other than legitimate channels;

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

(3) Any prior conviction record of the applicant under Federal or State laws related to controlled substances or to chemicals controlled under Federal or State law;

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

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

Like 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 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 be denied. *See, e.g. Energy Outlet*, 64 FR 14,269 (1999). *See also Henry J. Schwartz, Jr., M.D.*, 54 FR 16,422 (1989).

The Administrator finds that factors one and four are relevant to this case. The president/owner of Performance freely admitted his firm is a general contractor, and has no experience in handling listed chemicals. He further states he did not wish to manufacture the chemical, but only to make a one-time distribution pursuant to the request of a customer. There is no evidence concerning what measures, if any, Performance would take to prevent the diversion of the List I chemical. The DEA investigation showed Performance's proposed use of the chemical is not consistent with industry practice. The Administrator finds the public interest is not served by granting a DEA registration for a one-time distribution of a List I chemical to an entity with no experience in handling listed chemicals; having no intent to enter into the business of handling listed chemicals; for an alleged purpose inconsistent with industry practice; and where there is no evidence of controls to prevent the diversion of the chemical to the illicit manufacture of a Schedule I controlled substance.

Furthermore, granting this application would violate the long-standing DEA policy against "shelf registrations."

Therefore, for the above-stated reasons, the Administrator concludes that it would be inconsistent with the public interest to grant the application of Performance.

Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him

by 21 U.S.C. 823 adn 28 CFR 0.100(b) and 0.104, hereby orders that the application for a DEA Certificate of Registration submitted by Performance Construction, Inc., as a manufacturer and/or distributor, be denied. This order is effective April 14, 2002.

Dated: February 22, 2002.

**Asa Hutchinson,**  
*Administrator.*

#### **Certificate of Service**

This is to certify that the undersigned, on February 25, 2002, placed a copy of the Final Order referenced in the enclosed letter in the interoffice mail addressed to Wayne Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, DC 20537; and caused a copy to be mailed, postage prepaid, registered return receipt to Mr. Daniel V. Heleski, Performance Construction, Inc., 308 West Highland Drive, Lakeland, Florida 33813.

Karen C. Grant.

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## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **State Petroleum Inc.; Denial of Application**

On or about January 23, 2001, the Deputy Assistant Administration, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause (OTSC) by certified mail to State Petroleum, Inc. (State Petroleum), located in Dearborn, Michigan, notifying it of an opportunity to show cause as to why the DEA should not deny in application, dated June 17, 2000, for a DEA Certificate of Registration as a distributor of the List I chemicals ephedrine and pseudoephedrin, pursuant to 21 U.S.C. 823(h), as being inconsistent with the public interest. The order also notified State Petroleum that, should no request for hearing be filed within 30 days, the right to a hearing would be waived.

The OTSC was received, as indicated by the signed postal return receipt, received by DEA February 12, 2001. Since that time, no further response has been received from the applicant nor any person purporting to represent the applicant. Therefore, the Administrator of the DEA, finding that (1) thirty days having passed since receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that State Petroleum is deemed to have waived its right to a

hearing. After considering relevant material from the investigate file in this matter, the Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Administrator finds as follows. List I chemicals are chemicals 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 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 Administrator finds that on or about June 17, 2001, an application was received by the DEA Chemical Operations Registration section on behalf of State Petroleum for DEA registration as a distributor of the two above-mentioned List I chemicals. The DEA pre-registration inspection on July 7, 2001, revealed that State Petroleum had no prior experience in distributing List I chemical products. A corporate representative stated to DEA investigators that State Petroleum was in the business of wholesaling automotive chemical and petroleum products. The DEA inspection revealed State Petroleum appeared unprepared to accept the responsibilities of a DEA registrant. The inspection noted deficiencies in State Petroleum's proposed recordkeeping system that clearly show the firm's ability to comply with DEA's recordkeeping requirements. The DEA investigation also revealed a number of State Petroleum's proposed supplier was out of business and a random sampling of proposed customers either were not interested in distributing List I chemical products, or were already receiving List I chemical products from other suppliers.

Pursuant to 21 U.S.C. § 823(h), the Administrator may deny an application for a DEA Certificate of Registration if he determines that granting the registration would be inconsistent with the public interest. Section 823(h) requires the following factors be considered:

- (1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) Compliance by the applicant with applicable Federal, State, and local law;
- (3) Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to

chemicals controlled under Federal or State law;

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

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

Like 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 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 be denied. *See, e.g. Energy Outlet* 64 FR 14,269 (1999), *See also Henry J. Schwartz, Jr., M.D.*, 54 FR 16,422 (1989).

The Administrator finds factors one, four, and five relevant to this case.

Regarding factor one, the maintenance of effective controls against the diversion of listed chemicals, the DEA pre-registration inspection documented inadequate recordkeeping arrangements, in that State Petroleum intended to sell List I chemicals solely on a "cash and carry" basis, and there would be no computerized database with which to track sales to determine whether thresholds and recordkeeping requirements were being met. State Petroleum admitted that its proposed "cash and carry" plan for distribution of List I chemical products would be inadequate to meet DEA recordkeeping requirements.

Regarding factor four, the applicant's past experience in the distribution of chemicals, the DEA investigation revealed that State Petroleum has no previous experience related to handling or distributing listed chemicals.

Regarding factor five, other factors relevant to and consistent with the public safety, the Administrator finds that State Petroleum is unprepared to successfully meet the requirements of a DEA List I chemical registrant. State Petroleum admitted its proposed recordkeeping system would be inadequate to comply with DEA requirements. State Petroleum further could not explain any planned controls against diversion.

In addition, State Petroleum's proposed supplier was out of business, and a random sampling of its proposed customers either had no interest in List I chemical products, or were already receiving their List I chemical products from other suppliers. Thus State Petroleum failed to provide DEA with information demonstrating it had a legitimate source for List I chemical