

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, 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

Provedora 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 (Provedora) 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

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). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. As noted in previous DEA final orders, Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a persistent and growing problem in the United States. *Yemen Wholesale Tobacco and Candy Supply, Inc.*, 67 FR 9997 (2002); *Denver Wholesale*, 67 FR 99986 (2002).

The Deputy Administrator's review of the investigative file reveals that on March 25, 2003, Proveedora submitted an application for DEA registration as a distributor of the list I chemicals ephedrine and pseudoephedrine. The application was submitted on behalf of Proveedora by Mr. Jiron. Upon receipt of the application, the DEA Miami Field Division initiated a pre-registration investigation in or around April or May of 2003.

According to a DEA investigative report contained in the investigative file, on May 29, 2003, a DEA diversion investigator from the Miami Field Division contacted Mr. Jiron by telephone to schedule an appointment. Apparently, the investigator explained to Mr. Jiron that "information and documents" were needed to process the firm's application. There is no mention in the report of what specific information or documents were requested of Mr. Jiron. Mr. Jiron is quoted as replying to the investigator that he felt uncomfortable "divulging this information" although the investigator explained that all documents and information will remain confidential.

Similarly, a review of a July 15, 2003, certified letter from the DEA Miami Field Division to Mr. Jiron reveals a written reminder to the applicant of a prior discussion he had with DEA personnel where it was explained to that "information and documents were needed to in order to proceed with his application." Again, there is no reference in the aforementioned letter of what information was requested of Mr. Jiron for completion of his company's application for DEA registration.

According to the investigative file, the certified letter was returned to DEA unclaimed.

The investigative file further reveals that on August 18, 2003, a DEA diversion investigator telephoned an employee of Proveedora to verify the firm's address, and left a message for Mr. Jiron to contact the DEA apparently in regard to the firm's pending registration application. However, Mr. Jiron never contacted DEA regarding the matter.

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).

In rendering a final agency decision in this matter, the Deputy Administrator admittedly proceeds with great reluctance. Although a finding has been made that the applicant has waived its right to a hearing, nevertheless, the investigative file that has been provided ostensibly to assist the Deputy Administrator in rendering a ruling in this matter is at best, incomplete. The investigative file contains scant information about DEA's investigation of the applicant, virtually no information in any of the DEA investigative reports or correspondences on what information the agency requested of the applicant to complete

its investigation, and no background information which may have explained why the applicant declined DEA's repeated requests for additional information.

Nevertheless, in balancing public interest concerns and in response to the ongoing public health threat brought on by the diversion of list I chemical products, the Deputy Administrator finds the balance of interests weighs in favor of denying the application of Proveedora.

In its Order to Show Cause, the agency references the applicant's failure to provide requested documents or statements within a reasonable time, and how such inaction on the part of the applicant may be deemed a waiver by the applicant to present such matters for consideration by the Administrator pursuant to the "Additional information" provision found at 21 CFR 1301.15. Notwithstanding the above concerns surrounding the incomplete DEA investigative file, the Deputy Administrator agrees that the record is silent with respect to information that would support Proveedora's application. However, with respect to the agency's request for additional information relevant to an application for the registration of a list I chemical distributor, the appropriate regulatory provision is found at 21 CFR 1309.35, which is identical in scope to § 1301.15 in that it provides:

The Administrator may require an applicant to submit such documents or written statements of facts relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

It appears from the investigative file that the owners of Proveedora were not compliant with repeated DEA request for information necessary to the processing of its registration application. Such information is a necessary part of the investigative function in determining the fitness of an applicant to handle highly abused list I chemical products. DEA has previously found that an applicant's failure to provide information necessary to the completion of a pending application was a relevant determination in a decision to deny the application pursuant to 21 CFR 1309.35. *Callahan's Foods*, 68 FR 43750 (2003). *See also, CHM Wholesale Co.*, 67 FR 9985 (2002).

In light of the above, and the absence of evidence to the contrary, the Deputy Administrator is left to conclude that Proveedora cannot be entrusted with the responsibilities of a DEA registration. As a result, the Deputy Administrator further concludes that it would be inconsistent with the public interest to grant the application of Proveedora.

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 Proveedora Jiron, Incorporated, Edilberto Jiron, President, 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 LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

August 12, 2004.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor (DOL). To obtain documentation, contact Darrin King on 202-693-4129 (this is not a toll-free number) or e-mail: king.darrin@dol.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment Standards Administration (ESA), Office of Management and Budget, Room 10235, Washington, DC 20503, 202-395-7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the

functions of the agency, including whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment Standards Administration.

Type of Review: Extension of currently approved collection.

Title: Employer's First Report of Injury or Occupational Disease; Physician's Report on Impairment of Vision; and Employer's Supplementary Report of Accident or Occupational Illness.

OMB Number: 1215-0031.

Frequency: On occasion.

Type of Response: Reporting.

Affected Public: Business and other for-profit and not-for-profit institutions.

Number of Respondents: 21,060.

Form	Annual responses	Average response time hours	Annual burden hours
LS-202	21,000	0.25	5,250
LS-205	60	0.75	45
LS-210	2,160	0.25	540
Total	23,220	5,835

Total Annualized capital/startup costs: \$0.

Total Annual Costs (operating/maintaining systems or purchasing services): \$10,333.

Description: The Longshore and Harbor Workers' Compensation Act provides benefits to workers injured in maritime employment on the navigable waters of the United States and adjoining area customarily used by an employee in loading, unloading, repairing, or building a vessel. The Form LS-202 is used by employers

initially to report injuries that have occurred which are covered under the Longshore Act and its related statutes. The Form LS-210 is used to report additional periods of lost time from work. The Form LS-205 is a medical report based on a comprehensive examination of visual impairment. Regulatory authority is found in 20 CFR 702.201, 702.202, and 702.407.

Agency: Employment Standards Administration.

Type of Review: Extension of currently approved collection.

Title: Operator Controversion; Operator Response; Operator Response to Schedule for Submission of Additional Evidence; and Operator Response to Notice of Claim.

OMB Number: 1215-0058.

Frequency: On occasion.

Type of Response: Reporting.

Affected Public: Business or other for-profit and State, local, or tribal government.

Number of Respondents: 8,200.

Form	Annual responses	Average response time hours	Annual burden hours
CM-970	100	0.25	25
CM-970a	100	0.17	17