

orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry*.

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product*. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since 1998.

(7) If you are a U.S. producer of the *Domestic Like Product*, provide the following information on your firm's operations on that product during calendar year 2002 (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) The quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s); and

(c) The quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Countries*, provide the following information on your firm's(s') operations on that product during calendar year 2002 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from

each *Subject Country* accounted for by your firm's(s') imports;

(b) The quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country*; and

(c) The quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country*.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Countries*, provide the following information on your firm's(s') operations on that product during calendar year 2002 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in each *Subject Country* accounted for by your firm's(s') production; and

(b) The quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* since the *Order Date*, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise*

produced in the *Subject Countries*, and such merchandise from other countries.

(11) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry*; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

Issued: October 28, 2003.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Shani Distributors Denial of Application

On August 20, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Shani Distributors (Shani) proposing to deny its application, executed on October 21, 1999, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of Shani 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 Shani 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 Shani at its proposed registered location in Oklahoma city, Oklahoma. The return receipt indicated that the show cause order has been forwarded by the United States Postal Service to Shani at a second location where it was received on August 28, 2002. DEA has not received a request for hearing or any other reply from Shani or anyone purporting to represent the company in this matter.

Therefore, the 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 Shani has waived its hearing right. *See Aquí Enterprises*, 67 FR 12576 (2002). 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 1309.53(c) and (d) and 1316.67 (2003). The 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 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 illicit manufacture of methamphetamine and amphetamine. Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a growing problem in the United States.

DEA has obtained information that suggests a growing public health crisis in the State of Oklahoma concerning the abuse of methamphetamine. Contained within the investigative file is a chart prepared by the Oklahoma Bureau of Narcotics, which documents methamphetamine laboratory seizures by various law enforcement entities in that state. According to the chart, there were a total of 4,111 methamphetamine lab seizures in the State of Oklahoma from 1996 to 2002. In 2001 alone, there were 1,193 such seizures. In response to this public health threat, on May 22, 2002, the Governor of Oklahoma signed into law a provision which, among other things, makes it illegal under state law to possess or sell any product containing pseudoephedrine with intent to manufacture methamphetamine or another controlled substance. The new law also makes unlawful the sale of listed chemical products with the knowledge that they will be used as a precursor to manufacture methamphetamine. Okl. St., Sections 2-332, 2-333, See 21 U.S.C. 841(c).

The Administrator's review of the investigative file reveals that DEA received an application dated October 21, 1999, on behalf of Shani. The application was submitted by the company's owner, Tariq Maqsood (Mr. Maqsood). The applicant sought DEA registration as a distributor of the list I chemicals pseudoephedrine and phenylpropanolamine. On August 23, 2000, Mr. Maqsood submitted a letter to the DEA Oklahoma City District Office

requesting the withdrawal of pseudoephedrine from Shani's DEA registration application. Because Shani 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.

The Administrator finds that on March 10, 2000, DEA Diversion Investigators conducted a pre-registration inspection on Shani. DEA's investigation revealed that Shani, a sole proprietorship located in Oklahoma City, Oklahoma, specializes in the retail sale of tobacco products, vitamins, candy, and over-the-counter products such as aspirin and ibuprofen. At the time of DEA's on-site preregistration inspection, Shani was located at 532-B North Pennsylvania Avenue in Oklahoma City. The company was situated in a commercial warehouse area and was constructed with both brick and center block. The commercial roof was metal and rock design. Mr. Maqsood informed DEA investigators that in the event Shani's registration application was approved, list I chemical shipments would be received at the back warehouse door. That door was constructed of steel, secured by two sliding bars and a contact switch. After verification of the shipment, the chemicals were to be moved to a secured storage area. The customer entrance door was reinforced with glass and metal and secured with burglar bars, key-lock and the premises were secured with infrared motion detectors and an alarm system.

During the inspection, Mr. Maqsood further informed DEA investigators that he anticipated selling pseudoephedrine (60 mg., 60-ct. bottles) and phenylpropanolamine products to small convenience stores and food marts throughout the Oklahoma City area. Despite Mr. Maqsood's stated intent to sell listed chemical products, DEA's investigation revealed that Shani had no procedures in place to identify "suspicious" activity regarding a regulated transaction, in order to report such activity to DEA as required by 21 U.S.C. 830(b)(1)(A) and 21 CFR 1310.05(a)(1). Mr. Maqsood also informed DEA investigators that he had no experience with suspicious orders related to listed chemicals.

Mr. Maqsood further stated that Shani's sale of listed chemical products would be limited to approximately 48 bottles (or approximately eleven cases) per customer each month. When asked about potential suppliers of these products, Mr. Maqsood provided DEA investigators with the names of six

companies. The companies were located in the states of California or Texas.

DEA's investigation revealed that in 1997, one of Shani's prospective suppliers (hereinafter referred to as "JGKC"), located in Los Angeles, California received 90 million 60mg. tablets of pseudoephedrine, with most of the product diverted to clandestine methamphetamine labs in southern California. In March of that year, JGKC's ephedrine products were also discovered at a clandestine methamphetamine laboratory site in the Los Angeles area. DEA documented several additional instances where listed chemical products distributed by JGKC were eventually diverted to illicit uses.

DEA's investigation further revealed that a second prospective listed chemical supplier to Shani (hereinafter referred to as "AWD") supplied over six million tablets of ephedrine to a liquor store in 1996. Such distribution practices to a liquor store were apparently in excess of legitimate demand for these products. AWD's pseudoephedrine products were also discovered at a clandestine methamphetamine lab site in the State of California.

An investigation of a third prospective listed chemical supplier (hereinafter referred to as "IWI") revealed the sale of large quantities of pseudoephedrine to individuals involved in the illicit sale of listed chemicals in May 1996. DEA developed further information that in October 1996, law enforcement personnel seized 864,000 pseudoephedrine tablets from IWI in Dallas, Texas. Approximately one month later, an additional 432,000 pseudoephedrine tablets were seized from IWI on one occasion, and another 30 cases of that same product were subsequently seized. In 1998, IWI reported that it lost a shipment of 720 bottles of "Heads Up" 2-Way listed chemical product. In 1999, IWI was the intended recipient of 1,872 bottles of pseudoephedrine that were seized by law enforcement personnel in Upland, California. DEA further documented numerous excessive or suspicious purchases and sales of pseudoephedrine and ephedrine by IWI from 1993 to 2000.

As noted above, Mr. Maqsood submitted a letter to DEA requesting withdrawal of pseudoephedrine from his company's DEA registration application. As a result, on November 1, 2000, representatives from the DEA Oklahoma City District Office prepared a written memorandum of agreement (MOA) which contained conditions that would allow Shani to handle

phenylpropanolamine only. When asked about specific products he would handle, Mr. Maqsood mentioned pseudoephedrine products. DEA personnel informed Mr. Maqsood of differences between phenylpropanolamine and ephedrine, and further advised Mr. Maqsood that ephedrine was a Schedule IV controlled substance under Oklahoma law, thus requiring state licensure. Mr. Maqsood is not authorized under Oklahoma law to handle ephedrine, nor was the listed chemical included on Shani's application for DEA registration. Mr. Maqsood advised DEA that he would have his attorney review the proposed MOA, and requested a list of products that contained phenylpropanolamine. DEA subsequently provided the information. Mr. Maqsood never responded to DEA with respect to the proposed MOA.

On June 18, 2002, the DEA Oklahoma City District Office was contacted by the Oklahoma City Police Department (OCPD)—Methamphetamine (Investigations) Group regarding suspicious items observed at Shani. The officer informed DEA that while inside Shani, he observed 30–35 cases of "Heet;" brand gas line additive (a flammable solution with a chemical composition that includes methyl alcohol), approximately 8–10 cases of lithium batteries, lye and unspecified quantities of pseudoephedrine.

In response to this information, DEA investigators attempted to verify the observations of the OCPD officer by conducting a follow-up inspection of Shani. Upon their arrival, DEA investigators discovered that Shani had moved from the location and relocated to an address at 912 N. Pennsylvania in Oklahoma City. DEA had not received a request from Shani to modify its pending application for DEA Certificate of Registration, and DEA investigators have not performed an inspection of Shani's new business location.

On July 3, 2002, DEA investigators conducted verifications of Shani's customers. A review of the investigative file reveals that Shani's proposed customer base is comprised primarily of small convenience stores and/or food marts that sell gasoline. Shani provided to DEA a list of approximately 34 proposed customers located in or around the Oklahoma City area. DEA's investigation revealed that on February 27, 2001, the owners of two of the listed business establishments were convicted by a federal jury in the Western District of Oklahoma on charges related to the unlawful distribution of listed chemicals. Specifically, the two were convicted of conspiracy and unlawful

distribution of pseudoephedrine knowing or having reasonable cause to believe that the product would be used to manufacture methamphetamine, in violation of 21 U.S.C. 841(d)(2) and 846. Both were sentenced to terms of imprisonment exceeding 60 months.

DEA investigators conducted interviews and or inspections of nine business establishments listed by Shani as proposed customers. Of the nine establishments inspected, two revealed that they never heard of Shani; three indicated that they did not intend on purchasing listed chemical products from Shani; one firm disclosed that it had stopped selling pseudoephedrine for over a year; and one informed DEA investigators that it already had a listed chemical supplier. The two remaining business establishments were closed and boarded up.

On July 12, 2002, the DEA Oklahoma City District Office received a letter from the General Counsel for the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (the Bureau) regarding Shani's DEA registration application. The General Counsel argued that approval of Shani's application would be contrary to the public interest of the citizens of Oklahoma based in part upon " * * * an exponential growth in the number of clandestine methamphetamine laboratories seized" in that state. The letter further outlined the Bureau's alarm over the events of June 18, 2002, when the Oklahoma City Police Department observed large quantities of "Heet" gas line additive and batteries on the premises of Shani. The General Counsel found that these products "are widely used along with pseudoephedrine to manufacture methamphetamine, and * * * the combination of these three basic substances in one location is very consistent with involvement in such criminal activity." The General Counsel concluded that the Bureau was "aware of no legitimate reason why a chemical dealer would handle only or even primarily Heet, batteries and pseudoephedrine, unless he or she was catering specifically to those engaged in criminal drug manufacturing."

Pursuant to 21 U.S.C. 823(h), the 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 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 Administrator finds factors one, four and five relevant to Shani's pending application for registration.

With respect to factor one, maintenance of effective controls against the diversion of listed chemicals, DEA's pre-registration inspection documented adequate security measures taken by Shani with respect to the company's proposed storage of listed chemicals at its 532–B North Pennsylvania location. However, DEA's follow-up inspection of Shani revealed that the company has since abandoned that location and moved its operation to a second location. There is no evidence in the investigative file that Shani has requested modification of its pending application for registration to reflect a different business address, or that DEA has conducted a second pre-registration inspection of Shani to determine the adequacy of any security measures the company currently has in place.

With respect to factor four, the applicant's past experience in the distribution of chemicals, DEA's investigation revealed that the owner of Shani has no previous experience related to distributing or otherwise handling listed chemicals. The investigative file further revealed that Shani has no procedures in place to identify "suspicious" activity regarding a regulated transaction, in order to report such activity to DEA as required by 21 U.S.C. 830(b)(1)(A) and 21 CFR 1310.05(a)(1), and Mr. Maqsood has no experience with suspicious orders related to listed chemicals. This factor weighs against the granting of Shani's pending application. *See, Matthew D.*

Graham, 67 FR 10229 (2002); *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002). In addition, the Administrator finds factor four relevant to Mr. Maqsood's unfamiliarity with listed chemical products as evidenced by his statement to DEA investigators that he intended to distribute ephedrine products when not authorized to do so under Oklahoma state law. Mr. Maqsood further demonstrated his lack of familiarity with listed chemical products when he expressed confusion over the differences between combo-ephedrine products and products containing phenylpropanolamine.

With respect to factor five, other factors relevant to and consistent with the public safety, the Administrator finds this factor relevant to Shani's proposal to distribute listed chemical products primarily to convenience stores and combination food mart/gas station. 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*. The Administrator is further concerned about Shani's proposed customer base, particularly in light of the public health threat facing the State of Oklahoma and several surrounding states arising from the increased diversion of listed chemicals to the illicit manufacture of methamphetamine.

Notwithstanding the above concerns, the Administrator also finds factor five relevant to the results of DEA's verification of Shani's proposed customers. Among Shani's potential customers were two individuals convicted of felony charges related to the unlawful handling of listed chemicals, two that never heard of Shani, three that revealed their intent not to purchase listed chemicals from Shani, one that had stopped selling pseudoephedrine, and two establishments were closed and boarded up.

Factor five is also relevant to the chemical handling histories of Shani's proposed suppliers. The Administrator is concerned that Shani's proposed

suppliers have apparently engaged in distribution practices that has led to the diversion of large quantities of listed chemical products.

The Administrator also finds factor five relevant to Shani's possession and apparent sale of products that facilitate the illicit production of methamphetamine. In addition to listed chemicals such as pseudoephedrine, "Heet" gas line additive and other products containing methyl alcohol, lye, as well as lithium batteries, are products typically used in the illicit methamphetamine manufacturing process. These items are routinely discovered by law enforcement personnel at clandestine methamphetamine laboratory sites. *See, Clandestine Drug Labs, FBI Law Enforcement Bulletin*, April 2000. The Administrator has also learned that small-scale retailers in the Oklahoma City area have stockpiled hundreds and thousands of bottles of starting fluid and "Heet" products, even during times of the year when there is no apparent demand for the product. When a relatively small scale merchant packages and displays large quantities of such products alongside frequently diverted listed chemicals like pseudoephedrine, that person or entity, either knowingly or unknowingly, creates a climate conducive for the illicit manufacture of methamphetamine.

The Administrator finds relevant under factor five, the recommendation of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control that DEA not approve Shani's application for registration. The Bureau's recommendation was based in part upon concerns surrounding Shani's storage of large quantities of "Heet" and batteries, and how these products are catered to individuals engaged in the illicit manufacture of methamphetamine.

The Administrator finds factor five relevant to Shani's request to distribute phenylpropanolamine, and the apparent lack of safety associated with the use of that product. On November 6, 2000, the Food and Drug Administration (FDA) issued a public health advisory concerning phenylpropanolamine. *See, U.S. Food and Drug Administration, Center for Drug Evaluation and Research*, newsletter, November 6, 2000. In a study cited by the FDA, researchers have discovered that taking phenylpropanolamine increases the risk of hemorrhagic stroke (bleeding into the brain or into tissue surrounding the brain) in women. The study found that men may also be at risk for taking the drug. Although the risk of hemorrhagic stroke is very low, the FDA has

recommended that consumers not use any products that contain phenylpropanolamine.

In addition, FDA's Nonprescription Drugs Advisory Committee (NDAC) subsequently reviewed the above study and other information on phenylpropanolamine. *Id.* NDAC determined that there is an association between phenylpropanolamine and hemorrhagic stroke and recommended that the drug not be considered safe for over-the-counter use. FDA has requested that all drug companies discontinue marketing products containing phenylpropanolamine. In response to FDA's request, many companies voluntarily reformulated and are continuing to reformulate their products to exclude phenylpropanolamine while FDA proceeds with the regulatory process necessary to remove the drug from the market. *FDA's November 6, 2000 newsletter, supra*.

As of the date of this final order, the Administrator is unaware of whether the FDA has undertaken any regulatory action to remove phenylpropanolamine from the market. However, there is no information before the Administrator to refute recent findings that phenylpropanolamine may pose a health risk to users of the drug. In light of current data which suggests that phenylpropanolamine is unsafe for human consumption, the Administrator finds this factor also weighs against the granting of Shani's application for DEA registration. Based on the foregoing, the Administrator concludes that granting the pending application of Shani would be inconsistent with the public interest.

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 pending application for DEA Certificate of Registration, previously submitted by Shani Distributors be, and it hereby is, denied. This order is effective December 3, 2003.

Dated: September 16, 2003.

Karen P. Tandy,
Administrator.

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DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day notice of information collection under review: Violent