

*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