The Burke Museum is responsible for notifying the Confederated Tribes of the Umatilla Reservation, Oregon that this notice has been published.

Dated: December 6, 2005.

Sherry Hutt,

Manager, National NAGPRA Program.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–31]

Joey Enterprises, Inc. d/b/a/ NorthStar Wholesale Denial of Application

On March 2, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Joey Enterprises, Inc., d/b/a NorthStar Wholesale (hereinafter referred to as ''Respondent'') of Birmingham, Alabama. The show cause order proposed to deny the Respondent's February 10, 2003, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged in substance that granting the application of the Respondent would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h).

According to the DEA investigative file, on or about March 30, 2004, the Respondent, through its President Feroz Jiwani (Mr. Jiwani), requested a hearing in response to the show cause order. On April 22, 2004, the presiding Administrative Law Judge issued an Order for Pre-hearing Statements. As part of that Order, the Administrative Law Judge directed the Government to file its Pre-hearing Statement on or before May 14, 2004, and that the Respondent was to file its Pre-hearing Statement on or before June 4, 2004. Following pre-hearing motions extending the above scheduled filing dates, the Government filed its Pre-hearing Statement on July 21, 2004. However, the Respondent did not file its Pre-hearing Statement by the August 16, 2004 deadline.

On September 2, 2004, the Administrative Law Judge issued an order extending the filing date of the Respondent's Pre-hearing Statement to September 15, 2004. The Administrative Law Judge's Order also notified the Respondent that if it again failed to meet the deadline for filing a Pre-hearing Statement, such inaction would be deemed a waiver of its hearing entitlement. Nevertheless, the Respondent again failed to meet the new deadline and did not file its Pre-hearing Statement. Accordingly, on September 29, 2004, the Administrative Law Judge issued her Order Terminating the Proceedings.

The Deputy Administrator adopts the ruling of the Administrative Law Judge's termination order that the Respondent 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(b) and (d). 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). As noted in previous DEA final orders, pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. Methamphetamine is an extremely potent central nervous system stimulant and its illicit manufacture and abuse are ongoing public health concerns in the United States. *See e.g., Direct Wholesale,* 69 FR 11654 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.,* 67 FR 9997 (2002); *Denver Wholesale,* 67 FR 99986 (2002).

The investigative file contains a printed news release article from the DEA Web site regarding federal drug seizures and the abuse of methamphetamine in the State of Alabama. *http://www.dea.gov/pubs/states/alabama.html.* According to the article, methamphetamine has become the number one abused drug in Alabama. The article also tracked the ''dramatic increase'' in the number of methamphetamine laboratory seizures in the state from 1997 to 2003. According to data obtained by DEA's El Paso Intelligence Center (also known as ''EPIC''), in 1997, methamphetamine laboratory seizures in Alabama totaled six; by 2002, the total number of laboratory seizures climbed to 201.

The above-referenced registration application of the Respondent was initially submitted under the business name ''Joey Enterprises, Inc.,'' and was later amended to include the caption, ''d.b.a. Northstar Wholesale.'' The Respondent sought DEA registration as a distributor of the list I chemicals ephedrine, pseudoephedrine and phenylpropanolamine. There is no evidence in the investigative file that Respondent, or anyone purporting to represent the Respondent has sought to further modify its pending application.

The Deputy Administrator's review of the investigative file reveals that on September 3, 2003, DEA Diversion Investigators conducted an on-site pre-registration inspection at Respondent's proposed registered location in Birmingham. DEA's investigation revealed that Mr. Jiwani is the owner and President of the Respondent, his wife, Amynah, is the company's assistant manager, and the company also employs a part-time employee by the first name of Christopher. When asked by DEA investigators, neither Mr. nor Mrs. Jiwani knew the part-time employee's last name.

The Respondent is a cash and carry establishment that distributes typical convenience store items including tobacco products, candy, drinks and health and beauty products. The Respondent's customers consist of approximately 150 convenience stores and gas stations located in the Birmingham area, as well as Northern Alabama, Georgia and Fort Lauderdale, Florida.

DEA investigators asked Mr. Jiwani to provide information on list I chemical products the firm intended to carry. In response to the request, Mr. Jiwani provided a list of chemical products the firm would distribute, including: Max Brand 25/200 mg—60 count bottles; Mini Thins 25/200 mg—60 count bottles; Ephedrine 25/200 mg—60 count bottles; Bio Tech Ephedrine 25/200 mg—60 count bottles; Ephedrine 25/200 mg Black—12 count packets; Tylenol Cold, Tylenol Sinus and Tylenol Allergy (no sizes listed); Advil Cold and Sinus and Aleve Cold and Sinus (no sizes listed); and Vicks Dayquil and Nyquil (no sizes listed). Mr. Jiwani estimated that these products would make up ten to fifteen percent of Respondent's total sales.

Max Brand products have previously been identified by DEA as the ''precursor product predominantly encountered and seized at clandestine methamphetamine laboratories.'' See *Express Wholesale*, 69 FR 62086, 62087 (2004); see also, *RAM, Inc. d/b/a American Wholesale Distribution Corp.*, 70 FR 11693 (2005). Convenience stores are the ''primary source'' for the purchase of Max Brand products, which are the preferred brand for use by illicit methamphetamine producers. See *Elk International, Inc., d/b/a Tri-City Wholesale*, 70 FR 24615 (2005).

Mr. Jiwani also informed DEA investigators that he had no experience handling list I chemical products. He further stated that Respondent had no procedure in place for identifying suspicious or unusual purchases of list I chemical products.

According to the investigative file, on September 3 and 4, 2003, DEA investigators conducted random verifications of the ten of Respondent's proposed customers for list I chemical products. At least seven of the customers informed DEA personnel that they didn't carry listed chemical products or were already purchasing them from other suppliers. Another customer was already in possession of listed chemical products which were on display at the establishment. The customer insisted to DEA investigators that he purchased the products from Respondent, even when told that Respondent did not carry such products.

Mr. Jiwani further advised DEA investigators he requires new customers to provide tax exempt ID numbers before selling them anything. DEA investigators found however, that Mr. Jiwani could not confirm the existence of his customers because he did not visit the location of these stores prior to their becoming customers.

DEA has previously found that small, illicit laboratories operate with listed chemical products often procured, legally or illegally, from non-traditional retailers of over-the-counter drug products, such as gas stations and small retail markets. Some retailers acquire products from multiple distributors to mask their acquisition of large quantities of listed chemicals. See, *A–1 Distribution Wholesale,* 70 FR 28573 (2005).

DEA has further determined that there exists a ''gray market'' in which certain high strength, high quantity pseudoephedrine and ephedrine products are distributed only to convenience stores and gas stations, from where they have a high incidence of diversion. *A–1 distribution, supra,* at 28573. These gray market products are not sold in large discount stores, retail pharmacies or grocery stores, where sale of therapeutic over-the-counter drugs predominate. ''Two-way'' ephedrine and single entity pseudoephedrine products are prime products in this gray market industry and are rarely found in any retail store serving the traditional therapeutic market.

DEA has also credited industry data, market studies and statistical analysis which has shown that over 90% of over-the-counter drug remedies are sold in drug stores, supermarket chains and ''big box'' discount retailers. Less than one percent of cough and cold remedies are sold in gas stations or convenience stores. Studies have indicated that most convenience stores could not be expected to sell more than $20.00 or $40.00 worth of products containing pseudoephedrine per month. *Jay Enterprises of Spartansburg, Inc.,* 70 FR 24620 (2005).

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., *ANM Wholesale,* 69 FR 11652 (2004); *Energy Outlet,* 64 FR 14269 (1999). See also *Henry J. Schwartz, Jr., M.D.,* 54 FR 16422 (1989).

The Deputy Administrator finds factors four and five relevant to Respondent's pending registration application.

With regard to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant to Mr. Jiwani'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, e.g., *CWK Enterprises, Inc.* (CWK), 69 FR 69400 (2004); *Prachi Enterprises, Inc. (Prachi),* 69 FR 69407 (2004); *Matthew D. Graham,* 67 FR 10229 (2002); *Xtreme Enterprises, Inc.,* 67 FR 76195 (2002). Therefore, this factor similarly weighs against the granting of Respondent's pending application.

With respect to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor also weighs heavily against granting the Respondent's application. Methamphetamine abuse is one of the top public health threats facing the country. While there have been various state legislative initiatives enacted around the United States that seek to address the illicit production and use of methamphetamine, the growing menace of this drug remains a grave public health and safety concern. Ephedrine and pseudoephedrine are precursor products needed to manufacture methamphetamine and operators of illicit laboratories regularly acquire the precursor products needed to manufacture the drug.

Many of these illicit transactions arise from listed chemical products acquired from convenience stores and gas stations. It is apparent that the Respondent intends on being a participant in this market with most of its proposed customers made up 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., *ANM Wholesale,* 69 FR 11652 (2004); *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. Therefore, to Respondent's proposed sale of listed chemical products convenience store and gas stations weighs against granting its pending registration application.

As noted above, there is no evidence in the investigative file that the Respondent ever sought to modify its pending application with respect to listed chemical products it intends to distribute. Among the listed chemical products the firm seeks to distribute is phenylpropanolamine. 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 because of the apparent lack of safety associated with the use of this product. See e.g., *William E. ''Bill'' Smith d/b/a B &B Wholesale,* 69 FR 2259 (2004); *J &S Distributors,* 69 FR 62089 (2004); *Shani Distributors,* 68 FR 62324 (2003). The Deputy Administrator also finds factor

five relevant to the results of DEA's random customer verifications where several of Respondent's proposed customers informed investigators that listed chemicals products likely would not be purchased from Respondent.

Factor five is also relevant to Respondent's lack of procedure for identifying suspicious or unusual purchases of list I chemical products. Factor five is further relevant to DEA's investigative findings regarding Respondent's inability to confirm the existence of its customers. The Deputy Administrator is also somewhat concerned by the Jiwani's inability to identify a part-time employee. It is unknown whether any knowledge of the individual's identity would favorably or unfavorably impact DEA's determination with regard to Respondent's application for registration. Therefore, the unresolved nature of this event is also given consideration under factor five. Based on the foregoing, the Deputy Administrator concludes that granting the pending application of the Respondent 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 Joey Enterprises, Inc., d/b/a NorthStar Wholesale be, and it hereby is denied. This order is effective January 27, 2006.

Dated: December 15, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–63]

Donley D. Siddall, M.D.; Revocation of Registration

On June 28, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause to Donley D. Siddall, M.D. (Respondent) of Collegedale, Tennessee. The Order to Show Cause notified the Respondent of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AS691100, under 21 U.S.C. 824(a)(3), and deny any pending application for renewal of that registration pursuant to 21 U.S.C. 823(f). The Order to Show Cause further informed the Respondent of the immediate suspension of his registration, alleging that his continued registration would constitute an imminent danger to the public health and safety, pursuant to 21 U.S.C 824(d).

Specifically, the Order to Show Cause alleged in relevant part that effective January 7, 2004 the Tennessee Board of Medical Examiners (Tennessee Board) revoked Respondent's license to practice medicine in that state and as a result, he is not currently authorized to handle controlled substances in Tennessee.

By letter dated August 6, 2004, the Respondent, through his legal counsel, timely requested a hearing in this matter. As part of his hearing request, the Respondent asserted that ''* * * [t]he Tennessee Board * * * wrongly revoked [his] medical license * * *.'' On August 26, 2004, the presiding Administrative Law Judge Gail A. Randall (Judge Randall) issued to counsel for DEA as well as the Respondent on Order for Prehearing Statements.

In lieu of filing a Pre-hearing Statement, counsel for DEA filed Government's Request for Stay of Proceedings and Motion for Summary Disposition on September 9, 2004. In its motion, the Government recited the primary allegation raised in the Order to Show Cause regarding the January 7, 2004 revocation of the Respondent's Tennessee medical license. In support of its motions, the Government attached a copy of the aforementioned revocation order of the Tennessee Board. Accordingly, the Government argued that a motion for summary disposition is appropriate in this matter and Respondent's DEA Certificate of Registration should be revoked.

On September 29, 2004, counsel for the Respondent filed a Response In Opposition to the Government's Motion for Summary Disposition. In his reply brief, the Respondent argued in relevant part that any action by DEA to dismiss Respondent's right to a hearing would be ''premature'' since the matter involving the appropriateness of the Tennessee Board's revocation action was being reviewed in state courts. The Respondent also requested that DEA stay the current administrative action until the Tennessee state courts have reached a final decision regarding his state medical license. While he further argued in his reply brief that the Tennessee Board's revocation action was conducted ''* * * in an arbitrary and capricious manner'', and that the matter was pending review before the Tennessee courts, the Respondent nevertheless did not deny that he is currently without authorization to handle controlled substances in Tennessee, the state in which he currently holds a DEA registration.

On November 4, 2004, Judge Randall issued her Order, Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Randall granted the Government's Motion for Summary Disposition and found that the Respondent lacked authorization to handle controlled substances in Tennessee. In granting the Government's motion, Judge Randall also recommended that the Respondent's DEA registration be revoked. No exceptions were filed by either party to Judge Randall's Opinion and Recommended Decision, and on December 7, 2004, the record of these proceedings was transmitted to the Office of the DEA Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Decision of the Administrative Law Judge.

The Deputy Administrator finds that the Respondent currently possesses DEA Certificate of Registration AS6911007, and is registered to handle controlled substances at a location in Collegedale, Tennessee. As outlined above, the Respondent is currently without authorization to practice medicine in Tennessee following the January 7, 2004, revocation of his state medical license. Notwithstanding the Respondent's request that the DEA administrative matter be stayed pending a resolution of his appeal of the Tennessee Board's revocation order, there is no evidence before the Deputy Administrator that the Respondent has been granted reinstatement of his Tennessee medical license. Therefore, it is reasonable to conclude that without the ability to practice medicine, the Respondent also lacks authorization to handle controlled substances in Tennessee.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently