the Office of the General Counsel (FOIA/Privacy Counsel) at the address listed on the USTP FOIA/Privacy Act Web site (*http://www.usdoj.gov/ust*). The envelope and letter should be clearly marked ''Privacy Act Request'' and comply with 28 CFR 16.40, *et seq.*

RECORD SOURCE CATEGORIES:

Sources of information contained in this system generally consist of the credit counseling and/or debtor education provider applicants, and those whose applications for approval or reapproval have been withdrawn by the applicant or granted, denied, or revoked by the United States Trustee(s); the applicants' references; interested third parties; federal and state agencies; and/or USTP personnel.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Gregg Brothers Wholesale Co., Inc.; Denial of Application

On April 26, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order To Show Cause to Gregg Brothers Wholesale Co., Inc., (Respondent) of Powell, Tennessee. The Show Cause Order proposed to deny Respondent's application for registration as a distributor of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on the ground that its registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(h). *See* Show Cause Order at 1.

The Show Cause Order specially alleged that methamphetamine production ''continues unabated within the Tennessee region,'' that the State ''has a large number of independent methamphetamine producers,'' and that the State leads DEA's southeast region in the number of clandestine laboratory seizures. *Id.* at 2. The Show Cause Order also alleged that ''several distributors in Tennessee were selling pseudoephedrine and ephedrine products to many of the same retail customers.'' *Id.* at 3.

The Show Cause Order alleged that Respondent's owner, Mr. Thomas Gregg, told DEA Diversion Investigators (DIs) that he intended to distribute both traditional pseudoephedrine products and non-traditional or ''gray market'' products, including products that have been found during seizures of clandestine laboratories. *Id.* at 4. The Show Cause Order further alleged that ''during the pre-registration inspection, the DIs found that Respondent had several pseudoephedrine products in its possession and that Mr. Gregg ''did not realize that these products contained pseudoephedrine.'' *Id.* The Show Cause Order also alleged that between 2002 and 2005, Respondent had made ''about 17 purchases of various pseudoephedrine products,'' and that ''[b]etween 2002 and 2004, [Respondent] sold about 200 orders of pseudoephedrine products to various convenience stores and similar retail establishments.'' *Id.* at 5.

The Show Cause Order next alleged that Respondent expected to sell List I chemical products ''to about 190 various convenience stores and similar retail establishments.'' *Id.* at 5. Finally, the Show Cause Order alleged that Respondent's owner had indicated that ''ephedrine 2-way products would be the largest volume'' List 1 chemical product. *Id.* at 5–6. The Show Cause Order also notified Respondent of its right to a hearing.

The Show Cause Order was served by certified mail, return receipt requested, and on May 4, 2005, Respondent acknowledged receipt. Thereafter, Respondent, in a letter dated June 1, 2005, but which was not received until June 9, 2005, requested a hearing; the matter was initially assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner.

On June 16, 2005, the Government moved to deny Respondent a hearing on the ground that Respondent had not timely filed its request. *See* 21 CFR 1301.43(a). On June 28, 2005, the ALJ issued a memorandum offering Respondent the opportunity to respond to the Government's motion by 4 p.m. on July 21, 2005. When, by August 26, 2005, no response had been received, the ALJ granted the government's motion. *See* Order Terminating Proceedings at 1. The ALJ also found that Respondent had not timely requested a hearing and thus concluded that it had waived its right to a hearing. *See id.* The ALJ then ordered that the proceeding be terminated. *See id.* at 2.

Thereafter, the investigative file was forwarded to me for final agency action. I adopt the ALJ's finding that Respondent has waived its hearing right and hereby enter this final order based on relevant material in the investigative file.

Findings

Respondent is a Tennessee Corporation which is located in Powell, Tennessee. Mr. Thomas Gregg is Respondent's President and owns all of its shares. Respondent distributes bait, groceries, candy, snack food, health and beauty items and novelty items to convenience stores and gas stations in East Tennessee, Virginia, Kentucky, and North Carolina. On August 15, 2002, Respondent applied for a registration to distribute the List I chemicals pseudoephedrine, ephedrine, and phenylpropanolamine (PPA).

While ephedrine and pseudoephedrine have therapeutic uses, they are easily extracted from lawful over-the-counter products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. *See* 21 U.S.C. 802(34); 21 CFR 1308.12(d). PPA can also be used to manufacture methamphetamine. In November 2000, the FDA issued a public health advisory regarding PPA based on a study that found that the use of PPA increases the risk of hemorrhagic stroke.[1]

Methamphetamine is a powerful and addictive central nervous system stimulant, *see A–1 Distribution Wholesale*, 70 FR 28573 (2005), and is a schedule II controlled substance. 21 CFR 1308.12(d). The illegal manufacture and abuse of methamphetamine pose a grave threat to this country. Methamphetamine abuse had destroyed numerous lives and families and has ravaged communities. The manufacture of methamphetamine also causes serious environmental harms because of the toxic nature of the chemicals used to make the drug.

The problem of methamphetamine abuse is especially serious in Tennessee. In 2004, law enforcement agencies seized 939 clandestine methamphetamine labs in the State. These seizures were the second largest per-state total in the nation.

On September 1, 2004, two DEA Diversion Investigators (DIs) visited Respondent at its proposed registered location to conduct a pre-registration investigation. The DIs met with Mr. Gregg, who told them that he intended to sell both traditional and non-traditional List I chemical products and that his suppliers included Sessions Specialty Company of Lewisville, North

[1] More recently, on December 22, 2005, the FDA issued a notice of proposed rulemaking, which proposed to reclassify over-the-counter PPA products as ''not generally recognized as safe and effective.'' U.S. FDA, Center for Drug Evaluation and Research, Phenylpropanolamine (PPA) Information Page *http://www.fda.gov/cder/drug/infopage/ppa/* (visited June 15, 2006).

Carolina, and Proactive Labs of Lithin Springs, Georgia. Among the non-traditional products which Respondent intended to sell were 2-way ephedrine products including bottles containing 48 tablets manufactured by Body Dynamics, Inc. (BDI). Of note, DEA has issued numerous warning letters to both BDI and ProActive Labs advising them that their products have been found at illegal methamphetamine labs. *See D & S Sales*, 71 FR 37607, 37608 (2006).

During the course of the investigation, the DIs found that Respondent had obtained several pseudoephedrine products (3 boxes of Tylenol Sinus Tablets and 1 box of Advil Cold and Sinus Tablets) from the Sessions Specialty Company. Mr. Gregg further told the DIs that he had sold some pseudoephedrine products to his customers. Respondent did not, however, have a DEA registration to distribute the products.

When told by the DIs that Respondent could not lawfully sell these products, Mr. Gregg told the DIs that he did not know that the products contained List I chemicals. According to the DIs, Mr. Gregg returned the List I products to the distributor. There is, however, an invoice dated October 11, 2004, documenting the sale of Tylenol Sinus Geltabs to a food market; this was a product which Respondent was required to return to its distributor because it contained pseudoephedrine.

A review of Respondent's purchase records shows that Respondent purchased pseudoephedrine products sixteen times between January 2002 and June 2004. Respondent's sales records further show that Respondent sold List I chemical products containing pseudoephedrine on approximately 160 occasions during the 2002 through 2004 time period.[2]

The DIs evaluated Respondent's security measures; the physical security of its premises appeared to be adequate. Mr. Gregg further told the DIs that he did not allow merchandise to be stored on trucks overnight. When the DIs discussed with Mr. Gregg the problem of List I chemical diversion into the illicit manufacture of methamphetamine, Mr. Gregg told the DIs that he was not responsible because he did not make methamphetamine himself and could not control what other people did.

Mr. Gregg provided the DIs with a customer list. The DIs determined that Respondent's customer list included seventeen establishments that were also customers of another firm (Rite, Inc.), which was then under investigation and ultimately surrendered its registration.

The DIs determined that Respondent did not have a current business license. Finally, the DIs conducted background checks on Mr. Gregg and his employees. The backgrounds checks found no adverse information on any of these individuals.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless the registration would be ''inconsistent with the public interest.'' In making this determination, Congress directed that I consider the following factors:

(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.

Id.

''These factors are considered in the disjunctive.'' *Joy's Ideas*, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether an application for registration should be denied. *See, e.g., David M. Starr*, 71 FR 39367 (2006); *Energy Outlet*, 64 FR 14269 (1999). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). In this case, I conclude that factors one, two, and four are dispositive. Moreover, because the record establishes that Respondent has a substantial history of non-compliance with the registration provisions and that this provides ample reason for denying its application, I do not make any findings on factor five.

Factor One—Maintenance of Effective Controls Against Diversion

The investigative file does not establish that Respondent would fail to provide effective physical security to protect List I chemicals from theft. Moreover, Respondent appears capable of maintaining the required records. I have serious reservations, however, as to whether Respondent would report suspicious transactions.

During his discussions with the DIs regarding the diversion of List I chemicals, Mr. Gregg made statements to the effect that he was not responsible because he did not make methamphetamine himself and could not control what other people did. In light of the well documented problem of methamphetamine abuse in Tennessee, I find this statement extremely disturbing.

Recently, I ordered the revocation of a List I chemical distributor's registration in part because the registrant's attitude was that he was not responsible for diversion of his products into the illicit manufacture of methamphetamine after he delivered them to his customers. *See D & S Sales*, 71 FR 37607, 37610 (2006). In *D & S Sales*, the registrant had failed to report any suspicious sales notwithstanding that he clearly had reason to know that many of his customers were purchasing products in amounts that far exceeded legitimate demand. As I noted in *D & S Sales*, a registrant's attitude that it is not responsible for what happens to its product after delivery ''is fundamentally inconsistent with the obligations of a registrant.'' *Id.* Moreover, ''[t]his attitude is highly relevant in assessing the adequacy of [an applicant's] systems for monitoring the disposition of List I chemicals.'' *Id.*

As DEA has learned in cases such as *D & S Sales*, the effectiveness of our regulation which requires the reporting of suspicious transactions is dependent on registrants taking seriously their obligation to report. In short, Mr. Gregg's comments do not inspire confidence in his willingness to report sales of excessive quantities. I therefore conclude that Respondent would not maintain effective controls against diversion and that this factor supports a finding that Respondent's registration would be inconsistent with the public interest.

Factor Two—Compliance With Applicable Laws

The investigative file establishes that between 2002 and 2004, Respondent repeatedly violated the Controlled Substances Act when it engaged in approximately 160 distributions of List I chemical products without being registered to do so.[3] *See* 21 U.S.C.

[2] Approximately thirty-six of the invoices documented the sale of Alka-Seltzer Plus Cold. The invoices did not, however, specify whether these were in tablet or gelcap form. According to the manufacturer's web site, while Alka-Seltzer Plus Cold Liqui-Gels contain pseudoephedrine, the tablets do not. Because the investigative file does not establish the specific product sold, I do not count these sales as instances in which Respondent violated the CSA.

[3] Respondent's sales records indicate that it frequently sold several pseudoephedrine products on a single invoice. The 160 figure counts each

Continued

823(h); *id.* section 843(a)(9). Furthermore, according to Respondent's records, it sold List I chemical products even after the DIs conducted the on-site inspection and told Mr. Gregg that Respondent could not distribute these products without a registration. I thus conclude that Respondent's numerous and repeated violations of the CSA demonstrate that its registration would be inconsistent with the public interest and are reason alone to deny its application. I further note that Respondent did not produce a valid business license during the on-site inspection.

Factor Three—The Applicant's Prior Record of Relevant Criminal Convictions

There is no evidence that Respondent's owner, or any of its employees, has been convicted of a crime relating to controlled substances or chemicals under either Federal or State law. This factor ordinarily supports a finding that Respondent's registration would not be inconsistent with the public interest. But in this case, I decline to give the factor any weight because of the evidence establishing Respondent's non-compliance with the CSA.

Factor Four—The Applicant's Past Experience in the Distribution of Listed Chemicals

According to a letter from Mr. Gregg, Respondent previously distributed ephedrine and pseudoephedrine during some unspecified period prior to these products becoming regulated. I do not, however, consider this to be relevant experience as it occurred before the adoption of the current regulatory scheme and thus does not address whether Respondent would comply with federal regulations. Furthermore, for the reasons discussed under Factor Two, Respondent's past experience in distributing List I chemicals involved approximately 160 distributions over a nearly three year period without being registered and Respondent sold pseudoephedrine even after the DIs expressly told Mr. Gregg that Respondent could not distribute pseudoephedrine products without a registration.

As I noted in *Sato Pharmaceutical, Inc.*, 71 FR 52165, 52166 (2006), there is simply no excuse for Respondent to have engaged in the repeated distribution of List I chemical products without a registration, or for Respondent's owner or employees to be unaware that several of the products it was distributing contained List I chemicals. Because Respondent's past experience in distributing List I chemicals manifests a lengthy failure of non-compliance with the CSA's registration requirements, I therefore conclude that granting Respondent's application would be inconsistent with the public interest. Finally, because of the seriousness and duration of these violations, I deem them dispositive of the ultimate issue and need not make findings on the remaining factor. *See Hoxie* v. *DEA*, 419 F.3d 477, 482 (2005); *Morall* v. *DEA*, 412 F.3d 165, 173 (2005).

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) and 0.104, I hereby order that the previously submitted application of Gregg Brothers Wholesale, Co., Inc., for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is, denied. This order is effective November 13, 2006.

Dated: September 29, 2006.

Michele M. Leonhart,

Deputy Administrator.

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invoice as a single distribution even if the invoice documented the sale of several pseudoephedrine products.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Integrity Wholesale, Inc.; Denial of Application

On July 12, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Integrity Wholesale, Inc., (Respondent) of Fairview, Tennessee. The Show Cause Order proposed to deny Respondent's application for a DEA Certificate of Registration as a distributor of the List I chemical pseudoephedrine, on the ground that issuance of a registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(h); Show Cause Order at 1.

The Show Cause Order specifically alleged that Respondent is a wholesale distributor of various products including batteries, disposable cameras, film, household goods and health and beauty aids, and that in September 2003, Respondent had applied for a registration to distribute pseudoephedrine products from its Tennessee location. Show Cause Order at 1–2. The Show Cause Order alleged that Respondent's owner, Mr. Andrew Splendorio, had informed DEA investigators that Respondent distributes products to all fifty states and that approximately eighty percent of the orders it receives are made by telephone or the Internet. *Id.* at 2.

The Show Cause Order alleged that Respondent provided DEA investigators with a list that included several hundred proposed customers. *See id.* at 2. The Show Cause Order alleged that the list included numerous non-traditional retailers of over-the-counter drug products including dive shops, paintball shops, gun shops, rafting and kayak shops, photo shops, audio stores, wildlife centers and zoos, publishing companies, and a theatre. *See id.* The Show Cause Order further alleged that the list included numerous individuals who were not listed as being affiliated with any particular business. *Id.*

The Show Cause Order alleged that the proposed customers ''have zero expectation of sales of over the counter drug products.'' *Id.* The Show Cause Order also alleged that only ''[a]n extremely small amount of face-to-face purchases'' of pseudoephedrine products occur in non-traditional retailers, and that DEA has found that these establishments ''purchase inordinate amounts of these products and become conduits for the diversion'' of these products into the illicit manufacture of methamphetamine. *Id.*

Finally, the Show Cause Order alleged that the illicit manufacture of methamphetamine continues unabated in Tennessee. *See id.* at 2. The Show Cause Order further alleged that DEA had noted a trend towards smaller capacity laboratories and that these laboratories often obtain precursor chemicals from non-traditional retailers. *See id.* at 2–3. The Show Cause Order also alleged that some non-traditional retailers obtain List I chemicals from multiple distributors and that these products are then diverted into the illicit manufacture of methamphetamine. *See id.*

The Show Cause Order was served on Respondent by certified mail, return receipt requested. On July 22, 2005, Respondent received the Show Cause Order as evidenced by the signed return receipt card. Notwithstanding that the Show Cause Order clearly stated that Respondent's failure to request a hearing within 30 days after the date of receipt of the Order would be deemed a waiver of its right to a hearing, Respondent did not request a hearing until September 27, 2005. In response, on October 5, 2005, the Government moved for summary disposition