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

contending that Respondent had failed to timely file its request for a hearing.

On October 7, 2005, the Administrative Law Judge (ALJ) issued a memorandum directing that Respondent file a response to the Government's motion. Thereafter, on October 13, 2005, Respondent filed a response stating that it had failed to timely file a request for a hearing because it was ''extremely busy and a little under staffed.'' Mr. Splendorio further admitted that he had failed to give the matter ''my immediate attention.''

On October 25, 2005, the ALJ issued an Order terminating the proceeding and directing that the investigative file be forwarded to me for final agency action. The ALJ specifically noted that Respondent had neither filed a timely request for a hearing nor a timely request for an extension of time to file a request for a hearing. The ALJ further found that Respondent had not presented sufficient grounds for failing to file a timely request and that Respondent had waived its right to a hearing.

Having reviewed the record as a whole, I concur with the ALJ's findings that Respondent has not presented a sufficient reason to excuse its failure to timely request a hearing and that Respondent has waived its right to a hearing. I therefore enter this final order without a hearing based on relevant material contained in the investigative file and make the following findings.

Findings

Pseudoephedrine is a List I chemical that, while having therapeutic uses, can be extracted from lawful non-prescription products and used to manufacture methamphetamine, a schedule II controlled substance. *See* 21 U.S.C. 802(34); 21 CFR 1308.12(d). As noted in numerous prior DEA orders, ''methamphetamine is an extremely potent central nervous system stimulant.'' *Sujak Distributors*, 71 FR 50102, 50103 (2006), *A–1 Distribution Wholesale*, 70 FR 28573 (2005). Methamphetamine abuse has destroyed lives and families, ravaged communities, and caused serious environmental harms. *Sujak*, 71 FR at 50103.

Respondent, which is registered as a Colorado Corporation, is located at 7905 Pinecrest Lane, Fairview, Tennessee. On September 24, 2003, Respondent's president, Mr. Andrew Splendorio, submitted an application on behalf of Respondent for a registration as a distributor of the List I chemical pseudoephedrine.

On March 10, 2004, a DEA Diversion Investigator (DI) conducted an on-site inspection at Respondent's proposed registered location and met with Mr. Splendorio. The firm is located in the basement and garage area of a two-story brick home. Access to the area is gained through a wooden door which has a dead-bolt lock. The building also has an electronic alarm system.

Mr. Splendorio informed the DI that Respondent is a wholesale distributor of assorted products including cameras, film, batteries, household items, health and beauty aids, and other items. The DI determined that Respondent's sales territory includes all fifty states, as well as Puerto Rico, the U.S. Virgin Islands, and American Samoa. Mr. Splendorio further told the DI that eighty percent of the orders Respondent receives are are placed by telephone, five percent are placed over the internet, and the remaining fifteen percent are placed with the firm's three salespersons who are located in Florida, Nevada, and Alaska.[1] Respondent's salespersons do not, however, handle products. Rather, Respondent uses the United Parcel Service (UPS) to ship its products.

According to the investigative file, Respondent proposed to distribute such products as Tylenol Sinus, Tylenol Allergy Sinus, Tylenol Cold, Advil Cold and Sinus, Sudafed, Claritin and Benadryl. According to a letter provided by Mr. Splendorio, Respondent would initially carry products that are packaged in single dose pouches of 1–2 tablets with 12 pouches in a sleeve. The letter further stated, however, that Respondent intended to eventually also sell ''the 2 smallest multiple dose [packages] offered by each brand.'' Respondent's intended supplier was Lil' Drug Stores Products, Inc.

The DI inspected Respondent's recordkeeping system and found it to be adequate. The DI also obtained a list of proposed List I chemical customers from Mr. Splendorio. The list included dive shops, paintball facilities, camera shops, photo labs, canoe and kayak businesses, pools and waterparks, several museums and zoos, several markets, and numerous individuals who were not listed as owning any particular business. Moreover, the customers were located throughout the United States.

The DI contacted several of the potential customers; the DI verified that Respondent was a supplier of each firm and uncovered no other adverse information. The DI also conducted background checks on Respondent's officers and employees; the checks found no derogatory information on any individual.

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, 39368 (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 and five are dispositive and establish that Respondent's application should be denied.

Factor One—Maintenance of Effective Controls Against Diversion

I acknowledge that Respondent would provide adequate physical security to protect List I chemical products in its possession from theft. I further acknowledge that Respondent's recordkeeping system appears adequate.

Respondent's proposed method of distributing pseudoephedrine does not, however, provide adequate controls to protect against diversion. As found above, most of Respondent's business is derived from telephone and internet orders and Respondent sells its goods to all fifty states, as well as Puerto Rico, the U.S. Virgin Islands, and American Samoa. Moreover, the orders are then shipped by UPS, a commercial carrier.

Under Federal law and DEA regulations, a distributor who uses a

[1] Respondent also employs an administrative assistant and a warehouse manager.

commercial carrier to distribute to a non-regulated person nine grams or more of pseudoephedrine in the course of a calendar month engages in a regulated transaction. *See* 21 U.S.C. 802(39)(A)(iv), *id.* section 830(b)(3); 21 CFR 1310.03(c), *id.* 1310.04(f). Federal law further provides that ''[i]t is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction.'' 21 U.S.C. 830(a)(3); *see also* 21 CFR 1310.07. Under DEA's regulations, ''[f]or sales to individuals * * * the type of documents and other evidence of proof must consist of at least a signature of the purchaser, a driver's license and one other form of identification.'' 21 CFR 1310.07(d).[2]

It seems highly likely that Respondent's sales would frequently exceed the threshold. Most significantly, Respondent does not appear to have in place any procedures to verify the identity of its customers, most of which are located outside of Tennessee and at a great distance from Respondent's three salespersons. I thus find that Respondent lacks effective controls to prevent diversion. While this factor is reason alone to conclude that granting Respondent's application would be inconsistent with the public interest, a discussion of factor five is also warranted.

Factor Five—Other Factors That Are Relevant to and Consistent With Public Health and Safety

The record establishes that Respondent's proposed customers are not participants in the traditional retail market for pseudoephedrine products. *See*, *e.g.* D & S Sales, 71 FR 37607, 37608–09 (2006); *Joy's Ideas*, 70 FR at 33197. Indeed, dive shops and paint ball facilities seem to be an even less likely source for legitimate consumer purchases of pseudoephedrine than convenience stores and gas stations, establishments which DEA has repeatedly found to be ''sources for the diversion of listed chemical products.'' *Joey Enterprises*, 70 FR 76866, 76867 (2005). Moreover, Respondent's customer list included numerous individuals with no listed business affiliation. Why these individuals would need to purchase pseudoephedrine from a wholesaler rather than a retailer is not clear.

DEA final orders have repeatedly recognized that ''there is a substantial risk of diversion of List I chemicals into the illicit manufacture of methamphetamine when these products are sold by non-traditional retailers.'' *Tri-County Bait Distributors*, 71 FR 52160, 52164 (2006). *See also Joy's Ideas*, 70 FR at 33199 (finding that the risk of diversion was ''real, substantial and compelling''); *Jay Enterprises*, 70 FR at 24621 (noting ''heightened risk of diversion'' should application be granted). Under DEA precedents, an applicant's proposal to sell into the non-traditional market weighs heavily against the granting of a registration under factor five. So too here.

I acknowledge that Respondent proposed to sell only name brand pseudoephedrine products in lower dosage counts. While these products have not been preferred by illicit methamphetamine manufacturers, they have nonetheless been subject to diversion. *See*, *e.g.*, *TNT Distributors*, 70 FR 12729, 12730 (2005). Indeed, in light of recently enacted restrictions on the sale of List I chemical products imposed by both Congress and numerous state legislatures, it is reasonable to expect that methamphetamine traffickers will resort to using increasing amounts of name-brand products.

As I recently explained, ''[b]ecause of the methamphetamine epidemic's devastating effects, DEA has repeatedly denied an application when an applicant proposed to sell into the non-traditional market and analysis of one of the other statutory factors supports the conclusion that granting the application would create an unacceptable risk of diversion.'' *Tri-County Bait*, 71 FR at 52164. Thus, even though Respondent proposes to distribute only name-brand pseudoephedrine products, the fact that its proposed customers are primarily non-traditional retailers (and also include individuals with no known business affiliation) and that it has no effective measures to identify its customers and determine whether their purchases would be to meet legitimate consumer demand, creates an unacceptable risk that its products would be diverted. Therefore, while I acknowledge that none of Respondent's officers or employees has a record of criminal convictions (factor three) and that the investigative file does not otherwise establish that Respondent would fail to comply with applicable laws (factor two), I conclude that granting Respondent's application would be inconsistent with the public interest. *See Joy's Ideas*, 70 FR at 33199 (registrant's ''lack of a criminal record, previous general compliance with the law and regulations and willingness to comply with regulations and guard against diversion, are far outweighed by [registrant's] intent to continue selling * * * pseudoephedrine exclusively in the gray market'').

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 application of Integrity Wholesale, 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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[2] For sales to a new customer that is ''not an individual * * *, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person's signature, electronic password, or other identification.'' 21 CFR 1310.07(e). A regulated person must also ''verify the existence and apparent validity of a business entity.'' *Id.* at 1310.07(b).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Premier Holdings, Inc.; Denial of Application

On October 20, 2005, the Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Premier Holdings, Inc. (Respondent), d/b/a/ Filmart, of Brooklyn, New York. The Show Cause Order proposed to deny Respondent's application for a DEA Certificate of Registration as a distributor of List I chemicals, 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 was proposing to distribute List I chemical products containing pseudoephedrine to various firms including convenience stores. *See* Show Cause Order at 3. The Show Cause Order alleged that DEA has determined that convenience stores constitute a non-traditional or ''gray market'' for products containing pseudoephedrine and that there is ''a high incidence of diversion'' of these products from these retailers into the illicit manufacture of methamphetamine, a Schedule II controlled substance. *Id.* at 2. The Show Cause Order also alleged that even traditional cold and cough products have been diverted into the illicit manufacture of methamphetamine. *Id.* at 2.

The Show Cause Order further alleged that Respondent's owner, Mr. Eugene Lefkowitz, told DEA investigators that