reconsideration of the ALJ's decision. *See* Govt. Resp. at 2. While the Government counsel did not remember the aforementioned telephone conversation, he did not dispute that Respondent's counsel may have asked him whether he had to file anything. *Id.* The Government further pointed out that Respondent's counsel did not contend that he had not received the ALJ's Order for Status Report, and that the Order, which the Government had not received, presumably clearly stated the deadline for filing the Status Report. *See id.* at 2–3.

The Government contended that whether Respondent should be permitted to file a status report was irrelevant because Respondent's state license had been suspended in November 2004 and had remained so since then. The Government further argued that ''Respondent still does not know when the state proceedings will end, and there is no assurance that Respondent will regain its state authority.'' *Id.* at 3. According to the Government, ''[t]he ALJ based her Decision on the fact that Respondent had no state authority to handle controlled substances at the time of the Decision. That fact was true at the time of the deadline for the status report, at the time of the Decision and is true at the present.'' *Id.* Therefore, the Government argued that there was no basis for the ALJ to reconsider her decision.

The ALJ denied Respondent's motion for reconsideration. Again, the ALJ noted that ''under the Controlled Substances Act it is clear that the DEA does not have statutory authority to maintain a registration if the registrant is without state authority to handle controlled substances in the state in which the registrant conducts business.'' Order Denying Resp. Req. for Recon. at 2. The ALJ then transmitted the record to me.[2]

Having considered the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's findings of fact and conclusions of law. I further adopt the ALJ's recommended decision to revoke Respondent's registration. I do not, however, adopt the opinion to the extent it suggests that it was ''unfair'' for this agency to revoke Respondent's Federal registration based on the State proceeding and that ''such an action is circular and may result in the Respondent being denied an opportunity to adjudicate the facts.'' ALJ Dec. at 6.

I acknowledge that the State's Administrative Complaint relied in part on my Order to Show Cause and Immediate Suspension of Registration. *See* Admin. Complaint at 3. But the state complaint did not rely solely on my action. The state complaint cited a variety of grounds under Michigan law for imposing sanctions including ''failing to comply with applicable Federal laws,'' *id.* at 2 (citing Mich. Comp. Laws § 333.7311(1)(f)); dispensing of ''controlled substances for other than legitimate medical purposes,'' *id.* (citing Mich. Comp. Laws § 333.7311(1)(g)); and ''if an officer or stockholder of the pharmacy lacks good moral character.'' *Id.* at 2–3 (citing Mich. Comp. Laws § 333.17768(2)(a)). The complaint further alleged that Respondent had violated these provisions of state law. *Id.* at 3–4. Furthermore, the State's Order of Summary Suspension was based on the ''careful consideration of the documentation filed'' in the State's administrative proceeding including the complaint. Order of Summary Suspension 1. The State's Order also provided a procedure for Respondent to petition for dissolution of the state suspension. *See id.*

I take the State on its word and conclude that its decision to summarily suspend Respondent's state license was not based solely on my order but was also based on its own evaluation of the evidence. Furthermore, as Respondent itself pointed out, the State proceeding has been ''an elongated and vigorously contested hearing,'' which included at least six days of hearings with the State putting on an expert witness. It is hard to imagine why a proceeding would take so long to litigate and require expert testimony if it did not involve an adjudication of the underlying facts. Thus, I do not accept the ALJ's conclusion that it is ''circular'' for this agency to revoke Respondent's registration based on the State's summary suspension order and that doing so ''may result in * * * Respondent being denied an opportunity to adjudicate the facts.'' ALJ Dec. at 6. Quite the opposite, it appears that the State entered its suspension order based on its own examination of the evidence; it further appears that Respondent has had a full and fair opportunity to litigate the facts in the State proceeding.

DEA's regulations make clear that the ALJ's decision is only a recommendation; it is not the final agency action. The revocation of Respondent's Federal registration becomes final only with this order. Yet in the interval between the ALJ's decision and the publication of this order, Respondent has submitted no evidence to show that the State has lifted its suspension.

As the ALJ correctly recognized, DEA has consistently held that a registrant may not hold a DEA registration if it is without appropriate authority under the laws of the state in which it does business. *See, e.g., Rx Network of South Florida, LLC*, 69 FR 62,093 (2004); *Wingfield Drugs, Inc.*, 52 FR 27,070 (1987). Respondent does not have authority under Michigan law to handle controlled substances. Therefore, it is not entitled to maintain its DEA registration. *See Rx Network of South Florida*, 69 FR at 62095.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b) and 0.104, I hereby order that DEA Certificate of Registration, No. AO6837477, issued to Oakland Medical Pharmacy be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of its registration be, and they hereby are, denied. This order is effective September 25, 2006.

Dated: August 15, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14045 Filed 8–23–06; 8:45 am]

BILLING CODE 4410–09–P

[2] I emphasize that there is no provision in DEA's regulations for either party to request reconsideration of an ALJ's recommended decision. See generally 21 CFR Subpart D. The appropriate means of challenging the ALJ's decision is to file exceptions. See 21 CFR 1316.66.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sujak Distributors; Denial of Application

On May 18, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Sujak Distributors (Respondent). 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 Respondent's registration would be inconsistent with the public interest. *See* U.S.C. 823(h).

The Show Cause Order specifically alleged that Respondent was proposing to sell ephedrine and pseudoephedrine products, which are precursors used in the manufacture of methamphetamine, to convenience stores, gas stations and liquor stores in the Davenport, Iowa area. *See* Show Cause Order at 2. The

Show Cause Order alleged that only a small percentage of sales of non-prescription ephedrine and pseudoephedrine products occur in these retail outlets and that these establishments are a primary supply source of these products for the illegal manufacture of methamphetamine. *See id.* at 1–2. The Show Cause Order further alleged that Respondent's proposed registered location was at a storage unit rental facility and that Respondent's unit was not ''sufficiently secure from entry from adjacent units.'' *Id.* at 2.

The Show Cause Order also alleged that Respondent's co-owner, Mr. Dennis Carney, had told DEA Diversion Investigators that ''25 to 35 percent of his business would consist of listed chemical product sales to convenience stores, liquor stores and gas stations.'' *Id.* The Show Cause Order alleged that ''the average small store could expect to sell monthly only about $15.00 to $40.00 worth of pseudoephedrine products.'' *Id.* at 3. Finally, the Show Cause Order alleged that methamphetamine is ''one of the most popular and widely abused drugs throughout the Midwest.'' *Id.* The Show Cause order also notified Respondent of its right to a hearing. *Id.* at 4.

The Show Cause Order was served on Respondent by certified mail, return receipt requested, and on June 3, 2005, Respondent acknowledged receipt. Since that time, neither Respondent, nor anyone purporting to represent it, has responded. Because (1) more than thirty days have passed since Respondent's receipt of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived its right to a hearing. *See* 21 CFR 1309.53(c). I therefore enter this final order without a hearing based on relevant material in the investigative file and make the following findings.

Findings

Ephedrine and pseudoephedrine are List I chemicals that, while having therapeutic uses, are easily extracted from lawful 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). As noted in numerous prior DEA orders, ''methamphetamine is an extremely potent central nervous system stimulant.'' *David M. Starr*, 71 FR 39367 (2006); *A–1 Distribution Wholesale*, 70 FR 28573 (2005). Methamphetamine abuse has destroyed lives and families, ravaged communities, and created serious environmental harms. *Starr*, 71 FR at 39637.

Respondent is organized as a partnership which is co-owned by Mr. and Mrs. Dennis Carney. The investigate file contains additional information suggesting that Mr. Greg Glowacki, an employee of Respondent, may also have a financial interest in Respondent. Respondent is located at 2501 N. Lincoln Ave, M–3, Davenport, Iowa. The location is a unit in a storage rental facility.

On July 16, 2004, Respondent, through its co-owner, submitted an application for a registration to distribute the List I chemicals ephedrine and pseudoephedrine. On November 18, 2004, two DEA Diversion Investigators (DIs) visited Respondent at its proposed registered location to conduct a pre-registration investigation. The DIs met with Mr. Carney and discussed the nature of Respondent's business. Respondent supplies general merchandise and seasonal items to convenience stores, gas stations, and liquor stores in the Davenport, Iowa area. Respondent's business includes customers in both Iowa and Illinois.

Mr. Carney advised the DIs that he was seeking registration in order to sell the following List I chemical products which contain ephedrine: Mini Two Way 12.5/200 mg. in 6 count packets, 12 count blister cards, and 48 count bottles; Twin Tabs 12.5/200 mg. in 48 count bottles; and Rapid Action 12.5/200 mg. in 48 count bottles. Mr. Carney further advised the DIs that neither he or his wife, nor his employee, had any experience in handling List I chemicals. Background checks on Mr. Carney, his wife, and Mr. Glowacki, did not find any adverse information.

Respondent's proposed registered location was a 10 foot by 20 foot unit in a rental storage facility with approximately 100 units. The facility's office hours were 9 a.m. to 5 p.m., Monday through Friday. All occupants have access to the main corridor where Respondent's unit is located and can apparently obtain access to the facility at any time through use of a key-pad entry system. Moreover, the main corridor is wide enough so that a motor vehicle can be driven into the facility. The facility has at least two video cameras in place; one covers the main entrance, another covers the corridor adjacent to Respondent's unit and the loading dock. The entry system records the identification number of any person who has entered or exited the facility. In the event of a break-in, the security company notifies the local police department. Respondent's unit is protected by a padlock. Mr. Carney also told the DIs that he intended to purchase a steel storage cabinet for the List I chemical products. However, Mr. Carney has not provided documentation that the cabinet was in fact purchased.

Upon entering Respondent's storage unit, the DIs observed that the unit did not have a solid ceiling. Instead, the top of the unit was comprised of wire, which was run both length and width wise at perhaps one foot intervals.[1] The DIs found that the wire could easily be tampered with and that a person could gain access to Respondent's unit from other storage units.

The DIs also discussed with Mr. Carney his firm's business practices. Mr. Carney told the DIs that he did not have any procedures to determine whether new customers are legitimate purchasers other than visiting their businesses and ''checking them out.'' The DIs found that Mr. Carney understood the record-keeping requirements. Mr. Carney also appears to have adequate procedures for receiving and delivering List I chemicals. Mr. Carney further told the DIs that he would not engage in any transactions triggering the reporting threshold, *see* 21 CFR 1310.04 and 1310.05, and that he would contact DEA in the event a customer placed a suspicious order.

Subsequent to the pre-registration investigation, the DIs conducted customer verifications. The verifications did not uncover any adverse information.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless I determine that 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 combination of factors, and may

[1] The estimates of the interval is based on the photographs. No actual measurement was taken.

give each factor the weight I deem appropriate in determining whether a registration should be revoked or an application for a registration be denied.'' *Starr*, 71 FR 39368. *See also Energy Outlet*, 64 FR 14269 (1999). In this case, I conclude that factors one, four and five establish that Respondent's application should be denied.

Factor One—Maintenance of Effective Controls Against Diversion

The investigative file does not establish that Respondent would fail to properly comply with DEA's regulations pertaining to recordkeeping and reports. But ''the adequacy [of an] applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals,'' 21 CFR 1309.71(b)(8), is only one part of the inquiry under factor one.

Determining whether an applicant will provide proper physical security of listed chemicals is also critical in evaluating the effectiveness of an applicant's controls against diversion. *See* 21 CFR 1309.71(b). Here, the investigative file establishes that Respondent's proposed location does not provide adequate security for listed chemicals for several reasons. First, Respondent's storage unit lacks an adequate ceiling. Thus, even individuals who have lawful access to the facility could easily break in to the unit.

Second, DEA's regulations specifically mandate that I consider ''the extent of unsupervised public access to the facility.'' *Id.* 1309.71(b)(5). Here, there are 100 rental units in the facility and it is apparent that a large number of people have access to the building. Beyond that, it appears that the facility has employees on-site only from Monday through Friday, and only between the hours of 9 a.m. to 5 p.m. The facility is however, accessible 24 hours a day, every day of the year. Thus, access to the facility is largely unsupervised.

Moreover, Respondent does not know whether any of the other tenants have criminal records. Nor does it control who the landlord rents to. While Respondent's owner claimed to the DIs that no other occupant of the facility would be aware that he was handling List I chemicals, it is certainly possible, if not likely, that other occupants would eventually find out either through word of mouth or by observing Respondent's employees. Perhaps none of the other tenants (and the acquaintances they may bring to the facility) is a criminal, but this is a risk I decline to assume. I thus conclude that Respondent's proposed registered location does not provide adequate security for storing listed chemicals. This factor thus weighs heavily in support of denying Respondent's application.[2]

Factors Two and Three—Compliance With Applicable Law and the Applicant's Prior Record of Relevant Criminal Convictions

While there is evidence that Respondent failed to comply with Federal regulations when it was run by its previous owner, I have already concluded that those violations are not relevant. The more important question is whether there is any evidence that either the co-owners of Respondent or its employee have failed to comply with applicable Federal, state or local laws. The investigative file does not establish that any of these persons has failed to comply with applicable laws. Relatedly, none of these persons has been convicted of a criminal offense relating to controlled substances or chemicals. I thus conclude that both of these factors support granting Respondent's application.

Factor Four—Past Experience in the Manufacture or Distribution of Controlled Substances

Neither of Respondent's co-owners, nor its sole employee, have any prior experience in the manufacture or distribution of List I chemicals. Because of the potential for diversion, DEA has repeatedly held that an applicant's lack of experience in distributing List I chemicals is a factor which weighs heavily against granting an application for registration. *See, e.g., Starr*, 71 FR at 39368; *Jay Enterprises*, 70 FR 24620, 24621 (2005); *ANM Wholesale*, 69 FR 11652, 11653 (2004). The fact that neither of Respondent's co-owners, nor its employee, has any experience thus provides a substantial reason to deny the application.

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

Numerous DEA cases recognize that the sale of certain List I chemical products by non-traditional retailers is an area of particular concern in preventing diversion of these products into the illicit manufacture of methamphetamine. *See, e.g., Joey Enterprises*, 70 FR 76866, 76867 (2005). As *Joey Enterprises* explains, ''[w]hile there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to [gas stations and convenience stores], DEA has nevertheless found that [these entities] constitute sources for the diversion of listed chemical products.'' *Id. See also TNT Distributors*, 70 FR 12729, 12730 (2005) (special agent testified that ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores''); *OTC Distribution Co.*, 68 FR 70538, 70541 (2003) (noting ''over 20 different seizures of [gray market distributor's] pseudoephedrine product at clandestine sites,'' and that in an 8-month period distributor's product ''was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone.''); *MDI Pharmaceuticals*, 68 FR 4233, 4236 (2003) (finding that ''pseudoephedrine products distributed by [gray market distributor] have been uncovered at numerous clandestine methamphetamine settings throughout the United States and/or discovered in the possession of individuals apparently involved in the illicit manufacture of methamphetamine'').

Moreover, during clandestine lab seizures, DEA has frequently found high count List I chemical products, thus indicating that these are the preferred products for illicit methamphetamine manufacturers. *See OTC Distribution*, 68 FR at 70541, *MDI Pharmaceuticals*, 68 FR at 4236. Respondent proposed to sell similar high count products.

Significantly, all of Respondent's proposed customers participate in the non-traditional market for ephedrine and pseudoephedrine products. DEA final orders recognize 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. *See, e.g., 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); *Xtreme Enterprises*, 67 FR at 76197. 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.

Furthermore, 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. Thus, in *Xtreme Enterprises*, my predecessor denied an application

[2] Having concluded that Respondent's proposed location does not provide adequate security, I do not decide whether Respondent has adequate procedures for verifying the legitimacy of customers.

observing that the respondent's ''lack of criminal record, compliance with the law and willingness to upgrade her security system are far outweighed by her lack of experience with selling List I chemicals and the fact that she intends to sell ephedrine almost exclusively in the gray market.'' 67 FR at 76197. More recently, I denied an application observing that the respondent's ''lack of a criminal record and any intent to comply with the law and regulations are far outweighed by his lack of experience and the company's intent to sell ephedrine and pseudoephedrine exclusively to the gray market.'' *Jay Enterprises*, 70 FR at 24621. *Accord Prachi Enterprises,* 69 FR 69407, 69409 (2004).

I also note that the State of Iowa recently enacted legislation making all ephedrine products Schedule V controlled substances. *See* 2005 Iowa Acts Ch.15, S.F. 169 (codified at Iowa Code Ann. 124.212 (West 2006)). Under Iowa law, all ephedrine products must be sold in licensed pharmacies. Therefore, it appears that none of Respondent's customers can now lawfully sell the products that Respondent proposed to distribute.[3] *See* Iowa Code Ann. 124.302. Relatedly, Respondent can not distribute ephedrine products without obtaining an Iowa controlled substances registration. *See id.* As I have previously explained, where, as here, state efforts to combat the illicit manufacture of methamphetamine are consistent with Federal policy, it is appropriate to give them due weight in determining whether the granting of a registration would be consistent with public health and safety. *See McBride Marketing*, 71 FR 35710, 35711 (2006); *Joy's Ideas*, 70 FR 33195, 33199 (2005). I thus conclude that granting Respondent's application would be inconsistent with public health and safety.

In summary, there are several factors which support the conclusion that granting the application would be inconsistent with the public interest. Respondent's proposed security measures are plainly inadequate and are thus grounds alone to deny the application. Moreover, Respondent lacks experience in the distribution of List I chemicals and proposes to sell into the non-traditional market. Furthermore, none of Respondent's customers can lawfully sell ephedrine products under Iowa law. I therefore conclude that granting Respondent's application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

[3] The Iowa Act also placed limits on the sale of pseudoephedrine products, generally limiting their sale to pharmacies except for packages of liquid, liquid capsule, and liquid-filled gel caps that contain 360 milligrams or less.

Respondent also has customers in Illinois. Respondent did not, however, include any customers from Illinois in its list of potential List I chemical customers. I therefore do not consider the effect of Illinois' recently enacted Methamphetamine Precursor Control Act.

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 Sujak Distributors for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is, *denied.* This order is effective August 24, 2006.

Dated: August 16, 2006.

Michele M. Leonhart,

Deputy Administrator.

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NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–369 and 50–370]

Duke Power Company LLC; Notice of Consideration of Issuance of Amendment to Facility Operating License and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating Licenses NPF–9 and NPF–17, issued to Duke Power Company (the licensee), for operation of the McGuire Nuclear Station, Units 1 and 2, located in Mecklenburg County, North Carolina.

The proposed amendment would revise the McGuire Nuclear Station's licensing basis to adopt the alternative source term radiological analysis methodology in accordance with Title 10 of the Code of Federal Regulations (10 CFR) section 50.67.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's public document room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner/requestor in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific