Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Compliant Form, Coordination and Review Section, Civil Rights Division

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: none. Civil Rights Division.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and Households. The information collected from the respondents is used to investigate the alleged discrimination, to seek whether a referral is necessary, and to provide information needed to initiate investigation of the complaint.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents is 1,400. It will take the average respondent approximately 30 minutes to complete the form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 700 total annual burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Deputy Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW, Washington, DC 20530.

Dated: February 19, 2004.

**Brenda E. Dyer,**

*Deputy Clearance Officer, Department of Justice.*

[FR Doc. 04–4032 Filed 2–24–04; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF JUSTICE

### Bureau of Alcohol, Tobacco, Firearms and Explosives

### Agency Information Collection Activities: Proposed Collection; Comments Requested

**ACTION:** 60–Day Notice of Information Collection Under Review: Records of Acquisition and Disposition, Collectors of Firearms.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until April 26, 2004. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott Thomasson, Chief, Firearms Enforcement Branch, Room 7400, 650 Massachusetts Avenue, NW., Washington, DC 20226.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

*Overview of this information collection:*

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Records of Acquisition and Disposition, Collectors of Firearms.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. The record keeping requirement is for the purpose of facilitating ATF's authority to inquire into the disposition of any firearm in the course of a criminal investigation.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that it take 3 hours per year for line by line entry and that approximately 172,250 licensees will participate.

(6) *An estimate of the total public burden (hours) associated with the collection:* There are an estimated 516,750 annual total burden hours associated with this collection.

*If additional information is required contact:* Brenda E. Dyer, Deputy Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: February 18, 2004.

**Brenda E. Dyer,**

*Deputy Clearance Officer, Department of Justice.*

[FR Doc. 04–4166 Filed 2–24–04; 8:45 am]

**BILLING CODE 4410–FY–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 01–10]**

### Branex, Incorporated; Revocation of Registration

On December 28, 2000, the then-Deputy Administrator of the Drug

Enforcement Administration (DEA), issued an Order to Show Cause and Immediate Suspension of Registration to Branex, Incorporated (Respondent). The Respondent was notified of a preliminary finding that pursuant to evidence set forth therein, it was responsible for, *inter alia,* the diversion of large quantities of pseudoephedrine into other than legitimate channels. In addition to the parties presenting evidence at a subsequent administrative hearing, the then-Administrator also ruled on an interlocutory appeal brought by Government counsel regarding the applicability of the Jencks Act to DEA administrative proceedings. The Acting 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 Order to Show Cause—Immediate Suspension Registration alleged, in substance, the following:

1. List I chemicals are legitimate chemicals that also may be used in the illicit manufacture of a controlled substance in violation of the Controlled Substances Act, 21 U.S.C. 802(34), 21 CFR 1310.02(a). Ephedrine and pseudoephedrine are list I chemicals which are commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance.

2. Mr. Frank Marquez is the owner and president of the Respondent. Respondent is a wholesale distributor of sundry items and over-the-counter medical preparations in the West Florida area. On November 10, 1997, Respondent submitted an application for registration as a distributor of the listed chemicals pseudoephedrine, ephedrine and phenylpropanolamine. In February 1998, DEA conducted a pre-registration inspection at which Mr. Marquez was provided a copy of DEA regulations related to the handling of listed chemicals. Mr. Marquez was advised of the suspicious transaction reporting requirements, and he volunteered that he would not engage in cash transactions. The Respondent's application for registration to distribute list I chemicals was approved on February 19, 1998.

3. Between July 23 and September 30, 1999, Respondent ordered approximately 2,592,000 tablets of pseudoephedrine from one manufacturer. In October 1999, Respondent attempted to obtain an additional 3–4 million tablets of pseudoephedrine from two other manufacturers. These amounts of pseudoephedrine are excessive for the short time periods between Respondent's registration with DEA and October 1999.

4. On September 14 and 15, 1999, law enforcement agencies seized approximately 11,300 bottles of pseudoephedrine from clandestine laboratories in California. The lot numbers of the tablets seized matched the lot numbers for tablets purchased by Respondent.

5. On October 15, 1999, DEA agents seized 4000 bottles of pseudoephedrine from a clandestine laboratory in Los Angeles, California. The Respondent had previously purchased 5,760 bottles of pseudoephedrine bearing the same lot number found on the bottles of pseudoephedrine seized in the clandestine laboratory.

6. On July 31, 2000, DEA investigators served an Administrative Inspection Warrant at the Respondent's registered premises. Pursuant to the warrant, required records of purchases and sales of listed chemicals were acquired. An inventory of the listed chemical product on hand was also taken on that date. More then 41 million dosage units of pseudoephedrine were on hand.

7. A subsequent review of purchase records revealed that during the period February 1998 to July 2000, Respondent purchased over 1.3 million bottles of the listed chemical pseudoephedrine from six different suppliers, including three manufacturers and three distributors. The DEA chemical registrations of two of the Respondent's earlier suppliers were revoked or suspended on public interest grounds for distribution activity related to the diversion of pseudoephedrine.

8. During September 2000, Respondent made three sales of 50 case lots of pseudoephedrine to a customer who paid cash and picked up the product from Respondent's location. Respondent failed to report this sale to DEA as a suspicious transaction.

9. During the month of October 2000, an audit of these records was conducted by DEA. An opening inventory of ''zero'' was assigned for the audit period beginning on February 19, 1998. The physical count of July 31, 2000, (388,699 bottles) was used as the closing inventory. A review of the purchase records indicated that Respondent received 1,354,164 bottles of pseudoephedrine. A review of sales records indicated that Respondent sold 867,084 bottles. The audit concluded that Respondent was unable to account for 98,371 bottles of pseudoephedrine.

10. The unaccounted for 98,371 bottles of pseudoephedrine product contained over nine million 60 mg. tablets. Such a quantity of pseudoephedrine is sufficient to illegally manufacture 350 to 400 kilograms of methamphetamine.

Based on his preliminary findings, and pursuant to 21 U.S.C. 824(d), 21 CFR 1309.44(a), as well as the authority granted under 21 CFR 0.100, the then-Deputy Administrator ordered the immediate suspension of the Respondent's DEA Certificate of Registration, 002330BNY, as a distributor of list I chemicals, effective immediately. The suspension was to remain in effect until a final determination was reached in these proceedings. By letter dated January 24, 2001, the Respondent, through its legal counsel, timely filed a request for a hearing on the issues raised by the Order to Show Cause—Immediate Suspension of Registration, and the matter was docketed before Administrative Law Judge Mary Ellen Bittner (Judge Bittner).

Following pre-hearing procedures, a hearing was held in Arlington, Virginia on July 19 and 20, 23 through 25, and August 7 through 10, and 28 and 29, 2001. At the hearing, both parties called witnesses to testify and introduced documentary evidence. During the July 20 portion of the proceeding, and in response to a request by Respondent's counsel for certain evidentiary items from the Government, Judge Bittner ruled that the Jencks Act, Title 18 U.S.C. 3500, applies to DEA administrative proceedings; and further ruled, that following the direct examination of Government witnesses and upon timely request by Respondent, the Government is required to supply not only statements made and adopted by Government witnesses that apply to their direct testimony, but also pertinent testimony of such witnesses in prior DEA administrative proceedings.

On July 23, 2001, counsel for the Government filed Government Motion in Opposition to Preliminary Ruling Regarding Respondent Request for Documents as Jencks Act Material (18 U.S.C. 3500) in the Form of Witnesses' Previous Testimony and Affidavits in All Prior DEA Administrative Hearings and Motion for Written Ruling in Anticipation of Interlocutory Appeal. By memorandum dated July 30, 2001, Judge Bittner issued a Memorandum to Counsel and Rulings on Motions, granting the Government's Motion for Written Ruling, and further certified the issue for interlocutory appeal pursuant to 21 CFR 1316.62. On August 3, 2001, the then-Acting Administrator received the Government's Interlocutory Appeal of the Ruling of the Administrative Law Judge Regarding the Applicability of the Jencks Act (18 U.S.C. 3500) to DEA Administrative Proceedings Pursuant to

Title 21 CFR Part 1316, Subpart D. The then-Administrator also accepted on behalf of the Respondent a response in opposition to the Government's interlocutory appeal.

In light of arguments raised by the referenced interlocutory appeal regarding the applicability of the Jencks Act to DEA administrative proceedings, and the likelihood that the matter will again be raised in the future DEA proceedings, the Acting Deputy Administrator has incorporated in the instant final order the then-Administrator's ruling on the interlocutory appeal. The Acting Deputy Administrator further adopts herein that then-Administrator's August 16, 2001, Order, summarized as follows:

The Jencks Act, 18 U.S.C. 3500, provides in pertinent part that:

(a) In any criminal prosecution brought by the United States, no statement or report in the possession of the United States which was made by a government witness or a prospective Government witness (other than the defendant) shall be the subject of subpoena, discovery, or inspection until said witness has testified on direct examination in the trial of the case.

(b) After a witness called by the United States has testified on direct examination, the court shall, on motion of the defendant, order the United States to produce any statement (as hereinafter defined) of the witness in the possession of the United States which relates to the subject matter as to which the witness has testified. If the entire contents of any such statement relate to the subject matter of the testimony of the witness, the court shall order it to be delivered directly to the defendant for his examination and use.

(c) The term ''statement'', as used in subsections (b), (c), and (d) of this section in relation to any witness called by the United States, means—

(1) A written statement made by said witness and signed or otherwise adopted or approved by him;

(2) a stenographic, mechanical, electrical, or other recording, or a transcription thereof, which is a substantially verbatim recital of an oral statement made by said witness and recorded contemporaneously with the making of such oral statement; or

(3) a statement, however taken or recorded, or a transcription thereof, if any, made by said witness to a grand jury.

In support of the argument regarding the applicability of the Jencks Act to DEA administrative proceedings, Judge Bittner and the Respondent relied upon the court ruling *Harvey Aluminum* v. *National Labor Relations Board,* 335 F.2d 749 (9th Cir. 1964) (Harvey). Prior to the decision in that case, the National Labor Relations Board (NLRB), pursuant to the decision in *NLRB* v. *Adhesive Products Corp.,* 258 F.2d 403 (2d Cir. 1958), had modified its regulations governing administrative hearings before the NLRB in an attempt to apply the principle announced in *Jencks* v. *United States,* 353 U.S. 657 (1957) (*Jencks* decision). However, the *Harvey* court found the NLRB's attempt insufficient. In response to the NLRB's arguments that the Jencks Act could not be applied in full measure to its proceedings, the *Harvey* court stated:

> The rule applies to proceedings of the Board because ''the laws under which these agencies operate prescribe the fundamentals of fair play. Their proceedings must satisfy the pertinent demands of due process.'' Whether the compulsion of the rule is constitutional or statutory, the Board may not avoid it by adopting regulations inconsistent with its requirements.

*Harvey,* 335 F.2d at 753. (Citations omitted).

The *Harvey* court concluded that the NLRB's regulation did not meet the Constitutional requirements of due process.

Subsequent to the *Harvey* decision, however, the Supreme Court of the United States found in the context of a criminal trial that violations of the Jencks Act did not rise to the level of denial of due process. ''[A]part from trials conducted in violation of express constitutional mandates, a constitutionally unfair trial takes place only where the barriers and safeguards are so relaxed or forgotten * * * that the proceeding is more a spectacle * * * or trial by ordeal * * * than a disciplined contest.'' *United States* v. *Augenblick,* 393 U.S. 348, 356 (1969) (citations omitted). With regard to the *Jencks* decision and the Jencks Act, the *Augenblick* Court stated: ''Indeed our *Jencks* decision and the Jencks Act were not cast in constitutional terms. They state rules of evidence governing trials before federal tribunals * * *'' Id. at 356. See also *United States* v. *James Barrett,* 178 F.3d 34, 54 (1st Cir. 1999), *cert. denied sub nom. Barrett* v. *U.S.,* 528 U.S. 1176 (2000); *Humberto Martin* v. *United States,* 109 F.3d 1177, 1178 (7th Cir. 1996); *United States* v. *Joseph Thomas, Sr.,* 97 F.3d 1499, 1502 (D.C. Cir. 1996); *United States* v. *Lam Kwong-Wah,* 924 F.2d 298, 310 (DC Cir. 1991); *John K. Lincoln* v. *Franklin Y.K. Sunn,* 807 F.2d 805, 816 (9th Cir. 1987), *cert. denied,* 498 U.S. 907 (1990); *Martin* v. *Maggio,* 711 F.2d 1273, 1283 (5th Cir. 1983), *cert. denied sub nom. Martin* v. *Louisiana,* 449 U.S. 998 (1980); *Sperling* v. *Unites States,* 692 F.2d 223, 227 (2d Cir. 1982). *See also Palermo* v. *United States,* 360 U.S. 343, 345 (1959) (stating with regard to the *Jencks* decision that the Court was ''[e]xercising our power, in the absence of statutory provision, to prescribe procedures for the administration of justice in the federal courts.'').

The Acting Deputy Administrator adopts the finding of the then-Administrator that from the cited authority, it is clear that the Jencks Act is a statutory rule of evidence governing federal trials, and that due process does not require its application. In light of the Supreme Court's decisions in *Augenblick* and *Palermo,* the then-Administrator discounted subsequent lower court decision applying the Jencks Act to agency administrative proceedings on a due process basis.

The then-Administrator concluded that a number of courts, including the United States Supreme Court, have expressly recognized that, by their plain language and intent, the *Jencks* decision and the Jencks Act apply only to federal criminal trials. *See Palermo* v. *United States,* 360 U.S. at 347–8 (''[In passing the Jencks Act] Congress had determined to exercise its power to define the rules that should govern in this particular area in the trial of criminal cases * * *''); *Lincoln* v. *Sunn,* 807 F.2d at 816; *Martin* v. *Maggio,* 711 F.2d at 1283; *Jeffery L. Silverman* v. *Commodity Futures Trading Commission,* 549 F.2d 28, 34 (7th Cir. 1977); *L.G. Balfour Co.* v. *Federal Trade Commission,* 442 F.2d 1, 25 n.8 (7th Cir. 1971)(''It is clear the Jencks Act does not bind the Commission. That statute, enacted to restrict the impact of the *Jencks case,* is by its very terms peculiarly concerned with and applicable to criminal judicial proceedings.'').

In footnote nine of its decision, the *Harvey* court suggest another possible basis for the application of the Jencks Act to NLRB proceedings. The court found that 29 U.S.C.A. 160(b) required that NLRB proceedings ''shall, so far as practicable, be conducted in accordance with the rules of evidence applicable in the federal district courts of the United States * * *'' The court then noted that ''[p]roduction of statements of the Jencks type would be required in a civil action in federal district court * * *'' *Harvey,* 335 F.2d at 758 n.9. The *Harveys* court thus recognized that by statute, the federal rules of evidence were made applicable to NLRB proceedings. The then-Administrator concluded that this situation was not applicable to the instant proceedings.

*In the Matter of Rosalind Cropper, M.D.,* 66 FR 41,040 (DEA 2001), the

then-Acting Administrator of DEA noted that the Federal Rules of Evidence (FRE) do not directly apply to DEA administrative proceedings. *Id.* at 41,041. The then-Acting Administrator of DEA noted that the Federal Rules of Evidence (FRE) do not directly apply to DEA administrative proceedings. *Id.* at 41,041. The then-Acting Administrator further noted that unless modified by agency rules, evidence is admitted in administrative proceedings in accordance with 5 U.S.C. 556(d) of the Administrative Procedure Act (APA). *Id.*

The then-Administrator reiterated that the Jencks Act is a rule of evidence governing criminal trials in federal courts. *Augenblick,* 393 U.S. at 356; *Palermo,* 360 U.S. at 345, 347–8; *Lincoln* v. *Sunn,* 807 F.2d at 816; *Martin* v. *Maggio,* 711 F.2d at 1283; *Silverman* v. *CFTC,* 549 F.2d at 34; *L.G. Balfour Co.* v. *Federal Trade Commission,* 442 F.2d at 25 n.8. The then-Administrator found the reasoning in *Cropper* applied with equal force to the instant case. As decided in *Cropper,* evidence is admitted in DEA administrative proceedings in accordance with section 556 of the APA, as modified by agency regulations. Neither the APA, the provisions of 21 CFR 1316.59 which govern the submission and receipt of evidence in these proceedings, nor any of the other regulations governing DEA administrative proceedings found at 21 CFR Part 1316, Subpart D, appear to contain any provision applying the *Jencks* decision or the Jencks Act to DEA administrative proceedings. The then-Administrator noted further that he was unaware of any published DEA final order that applied the Jencks Act to these proceedings.

In light of the cited authority and the plain language of the Jencks Act, the then-Administrator found that by its terms, the Jencks Act is not applicable and has not been made applicable to DEA administrative proceedings. The then-Administrator further found that there is no constitutional requirement that the Jencks Act be made applicable to DEA administrative proceedings. Accordingly, the then-Administrator concluded that pursuant to applicable law and regulations governing DEA administrative proceedings, neither the principles of the *Jencks* decision nor the Jencks Act are applicable to these proceedings. The then-Administrator further concluded that the Federal Advisory Committee Act, 5 U.S.C. Appendix, does not apply to DEA administrative proceedings, as 5 U.S.C. 556(d) and 21 CFR 1316.46(a) control the availability of transcripts of such proceedings.

Following the then-Administrator's ruling on the interlocutory appeal, and at the conclusion of the administrative hearing, both parties filed Proposed Findings of Fact, Conclusion of Law, and Argument. On December 4, 2002, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (Opinion and Recommended Ruling) recommending that the Respondent's registration as a distributor of list I chemicals be revoked. Both the Government and the Respondent filed Exceptions to the Administrative Law Judge's Opinion and Recommended Ruling. Thereafter on January 21, 2003, Judge Bittner transmitted the record of these proceedings to the then-Deputy Administrator for a final decision.

The Acting Deputy Administrator finds that 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). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. Phenylpropanolamine, also a list I chemical, is a legitimately manufactured and distributed product used to provide relief of the symptoms resulting from irritation of the sinus, nasal and upper respiratory tract tissues, and is also used for weight control. Phenylpropanolamine is also a precursor chemical used in the illicit manufacture of methamphetamine and amphetamine. Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a growing problem in the United States.

A ''regulated person'' is one who manufactures, distributes, imports, or exports *inter alia* a listed chemical. 21 U.S.C. 802(38). A ''regulated transaction'' is *inter alia,* a distribution, receipt, sale, importation, or exportation of a threshold amount of a listed chemical. 21 U.S.C. 802(39). The Acting Deputy Administrator finds all parties mentioned herein to be regulated persons, and all transactions mentioned herein to be regulated transactions, unless otherwise noted.

The Acting Deputy Administrator finds that the Respondent was founded in 1982, in Tampa, Florida as a wholesale distributor servicing independent grocery and convenience stores, as well as establishments operating vending machines. The Respondent's president, Frank Marquez (Mr. Marquez), has been with the company since its inception. At the time of the hearing, the Respondent had approximately seventeen employees on its payroll.

Mr. Marquez testified that he is a member of the American Wholesale Market Association and the National Candy Association. The Respondent, through the person of its president, is also director of the Vending Association of Florida (an organization comprised of approximately one hundred members), and director and vice president of the Florida Candy and Tobacco Wholesaler Association. The Respondent supplies its customers, merchandise from major domestic suppliers of candy and confectionary, meat, salty snacks, fruit juices and beverages, tobacco products, sundries and over-the counter medications.

As noted above, on November 10, 1997, Respondent submitted an application for DEA registration as a distributor of the listed I chemicals. On or around February 14, 1998, diversion investigators from DEA's Tampa District Office (the Tampa District Office) conducted an on-site pre-registration inspection of the Respondent's proposed registered location. As part of that inspection, investigators provided Mr. Marquez with a copy of DEA regulations and reference materials commonly referred to as the ''Red Sheet'' and the ''Green Sheet.'' These documents direct an applicants' attention to matters involving the diversion of ephedrine, pseudoephedrine and phenylpropanolamine to the illicit production of emphetamine and methamphetamine. The ''red'' and ''green'' notices further direct an applicants' attention to the requirement of a DEA registrant to report ''suspicious orders'' of list I chemical products. Following the inspection, DEA Diversion Investigator Miguel Soler recommended that the Respondent's application for registration be approved, and on February 19, 1998, DEA issued to the Respondent a DEA Certificate of Registration to distribute the list I chemical products listed on its registration application.

In her Opinion and Recommended Ruling, Judge Bittner found, that following the issuance of its DEA Certificate of Registration, the Respondent engaged in three different types of distribution businesses: (1) Selling pseudoephedrine in bottles and multi-dose blister packs to distributors and retailers; (2) supplying customers who stock vending machines with a variety of products, including, among others, sodas, over-the-counter medications, shavers, snacks, and toiletry items; and (3) through its subsidiary All Gourmet, selling high-

end chocolates, mints, and jellies to specialty retailers such as gift shops and firms that make gift baskets.

Mr. Marquez testified that in 1999 and 2000, candy and snack products accounted for about approximately 90 to 92 percent of the Respondent's business and that during that two-year period, Respondent's aggregate sales were $29 or $30 million. As of the date of Mr. Marquez's testimony at the administrative hearing, the value of Respondent's inventory of all products that it carried was approximately $2 million.

The Respondent presented further evidence that it services approximately 550 independent grocery stores, and that over the two years preceding the hearing in this matter, approximately 250 to 300 of those stores changed ownership, went out of business or changed names. Mr. Marquez testified that in March or April 1999, he decided to sell 60-count, 60 milligram pseudoephedrine to retail stores. A customer list dated June 29, 2001, and admitted into evidence revealed that in addition to customers in Florida, the Respondent had 265 pseudoephedrine customers in various parts of the United States including Michigan, Tennessee, Washington, New Jersey, Illinois, Oklahoma, and Texas, as well as six additional states.

Mr. Marquez testified that he hired two salesmen, Habeke Tekelewold (Mr. Tekelewold) and Mustafa Ahmad (Mr. Ahmad) who were responsible generally for coordinating the Respondent's sale of pseudoephedrine products to its various customers, and determining the suitability of those customers. Mr. Marquez assigned to Mr. Tekelewold the task of ensuring that customers were properly licensed, and checking individual stores to further ensure that Respondent's products were properly shelved. Mr. Marquez further testified that the Respondent also required every potential customer to execute an agreement which, among other things, required customers to ''comply with all applicable DEA regulations, including reporting suspicious inquiries immediately to both DEA and Neil Laboratories, Incorporated.'' At the time of the hearing, Neil Laboratories, a DEA-registered manufacturer/distributor, was a supplier of list I chemical products to the Respondent.

Mr. Marquez further testified that the Respondent employed specialized procedures for retail customers that wished to purchase over-the-counter drug products, including list I chemicals: a requirement of written purchase orders for all purchases of listed chemical products and the use of credit applications. Mr. Tekelewold testified that the Respondent also confirmed the identities of prospective retail customers by telephone, and following such contact, the Respondent would request copies of available business licenses. Upon receipt of those licenses, Respondent's personnel would conduct on-site visits.

Mr. Marquez also testified to specialized procedures for customers that wished to purchase list I chemical products for resale: The Respondent would obtain a copy of the prospective customers' DEA registration and a copy of the principal's driver's license. That information would be sent to the Tampa District Office, along with a request for review and reply. Investigator Soler testified that on at least one occasion, the Respondent notified DEA of a suspicious customer, and DEA subsequently issued an advisory to the Respondent not to sell list I chemicals to that customer, to which the Respondent complied.

In her Opinion and Recommended Ruling, Judge Bittner referenced testimony by Mr. Marquez that in February or March 2000, Respondent reduced its retail sale of pseudoephedrine products to 144 bottles per month; however, it appeared that some the 144-bottle cases contained 120-count bottles. Mr. Marquez further testified that toward the middle of 2000, he purchased approximately 776 cases of 120-count bottles and 785 cases of 100-count bottles of pseudoephedrine from Over-The-Counter Distribution Company (OTC Distribution), a list I chemical distributor located in Dallas, Texas, because the opportunity arose to buy in that quantity and Respondent had some difficulty obtaining enough pseudoephedrine to meet demand.

Mr. Tekelewold testified that Respondent imposed a standard fee for $110 for overnight shipping of a case of pseudoephedrine and charged $50 for regular shipping, which would take approximately two or three days. Mr. Marques, testified however, that shipping for receipt the next day would cost $60 or $70 and shipping for receipt two days later would cost $45 or $50. Further evidence was presented that the choice of shipping arrangements was contingent upon how quickly the customer wanted to receive the product.

Mr. Tekelewold further testified that for two years, he owned five gasoline stations in Florida, all of which he sold in 1999. According to Mr. Tekelewold, those gas stations sold candy, snacks, cold drinks, beer, cigarettes, and over-the-counter medication such as Sudafed, Tylenol, and Alka-Seltzer, in addition to gasoline. Mr. Tekelewold added that he sold these other products because :''[y]ou cannot survive only by selling gas * * *''

In addition, Mr. Tekelewold testified that he did not handle non-pseudoephedrine products for any of Respondent's customers except the gasoline stations he owned. Nevertheless, Judge Bittner noted, and the Acting Deputy Administrator concurs, that notwithstanding Mr. Tekelewold's testimony that some of Respondent's pseudoephedrine customers purchase other products from Respondent, there was no evidence to this effect in the record.The Respondent maintains a catalogue of its products, and those products are organized by product codes. For example Code 290 is ''HBA (Health and Beauty Aid)—headache.'' Code 301 is listed as ''HBA nasal care.'' Pseudoephedrine products distributed by the Respondent are not listed in the Health and Beauty Aids section of the catalogue. Rather, the product is listed under Code 699—Grocery and General Merchandise. Mr. Marquez testified that he listed pseudoephedrine in this manner as a control measure to prevent every single customer from asking for these type of products.

The Government presented evidence regarding DEA's issuance or warning letters to DEA-registered handlers of listed chemicals. DEA warning letters generally advise chemical registrants that their chemical product has been discovered at clandestine laboratory settings and how the registrants' distribution patterns may have contributed to the diversion of these products to the illicit manufacture of methamphetamine. These warning letters are issued by agency's Office of Diversion Control under its precursor chemical control program.

Kevin Lee, a program analyst form the Office of Diversion Control testified on behalf of the Government. Mr. Lee testified that there are three situations where DEA warning letters are issued: where there is a clandestine laboratory seizure; at clandestine laboratory dump sites, where discarded bottles and related packaging are discovered; and in situations involving precursor trafficking.

As of the date of the hearing in this matter, DEA had never issued a warning letter to the Respondent. However, Mr. Lee reviewed a compilation of the Respondent's receipt and purchase of list I chemical products from five entities that manufactured and/or distributed list I chemicals. With respect to these entities, DEA had issued approximately 114 warning letters

regarding the diversion of listed chemicals.

Further evidence was presented that the Respondent purchased from OTC Distribution 28,368 bottles of pseudoephedrine products with the same lot number as that which was the subject of a warning letter dated November 15, 2000, to Adams Laboratories, Incorporated (Adams). Adams, a manufacturer of list I chemicals, had previously sold the product to OTC Distribution. DEA sent additional warning letters to Adams on January 25 and February 5, 2001. By letter dated February 19, 2001, Adams directed its customer Wildcat Wholesale Distribution not to sell Adams' list I chemical products to certain named distributors, including the Respondent.

DEA further presented the testimony of the manager of the Precursor Compliance Program for the California Bureau of Narcotic Enforcement (BNE), who testified that California has the largest number of clandestine laboratory seizures in the United States and methamphetamine is ''the number one drug problem in the state.'' The government witness testified that in 1986, California established a clandestine lab enforcement and precursor program to counter illegal methamphetamine production in the state. To that end, California has also established a warning letter program similar to DEA's whereby letters are issued to listed chemical distributors notifying these firms that their list I chemical products had been discovered as clandestine laboratory setting.

The government witness further testified that in 2000, the State of California issued warning letters to two of the Respondent's list I chemical suppliers as a result of their product being found at a clandestine setting in the city of San Jose. It was subsequently determined that lot numbers of some of the chemical products found at that location were the same as those of product shipped to the Respondent and other distributors.

In or around May 2000, the Tampa District Office learned that the Respondent had received large quantities of pseudoephedrine from various suppliers, including more than twenty-four million tablets from OTC Distribution. In response to this information, on July 31, 2000, diversion investigators from the Tampa District Office served an administrative inspection warrant on Mr. Marquez, authorizing the seizure of the Respondent's records of the sale and receipt of pseudoephedrine from July 31, 1998 to the date of the warrant.

By all accounts, Mr. Marquez was cooperative in providing the requested records to DEA investigators and taking an inventory of the number of pseudoephedrine bottles his company had on hand. That inventory was conducted as part of a DEA audit of the Respondent's handling of list I chemicals over the then-two year period (1998 to 2000) of the Respondent's registration with DEA. Diversion Investigator Solar also compiled a listing of all sales of pseudoephedrine by the Respondent. Specifically, Investigator Solar created a document which chronicled the names of the listed chemical products purchased by the Respondent, date of purchase, name of company that sold the product to the Respondent, lot number, the number of cases, number of bottles per case, and the number of pseudoephedrine tablets. Investigator Solar then turned over Respondent's invoices and other documentation to the National Drug Intelligence Center (NDIC) for completion of the audit. NDIC in turn, prepared a spreadsheet of all of the Respondent's transaction from the registrant's invoices, and also compiled a listing of the Respondent's purchases of pseudoephedrine.

For the inventory, DEA investigators used an opening date of February 19, 1998, with an opening balance of zero. When a zero balance is used as part of an accountability audit, it operates as an assumption that a registrant does not have any of the audited products on hand as of the beginning date of the audit period. A zero opening inventory will also result in audit figures that understate any shortages or overages that may be uncovered. For example, if a registrant has list I chemical products on hand when an audit is initiated, but investigators instead decide that a zero balance will be used, those products on hand will not be considered a part of the audit for which the registrant is accountable. Therefore, for audit purposes, a zero opening inventory typically works in favor of the registrant.

On July 31, 2000, DEA investigators performed a physical count of pseudoephedrine bottles on hand which totaled 388,699 bottles. This total was used as the closing inventory. Further review of Respondent's purchase records revealed that the firm received 1,354,164 bottles of pseudoephedrine, and its sales records revealed the sale of 867,084 bottles of pseudoephedrine between the opening of business on February 19, 1998 and July 31, 2000. The audit concluded that the Respondent was unable to account for 98,381 bottles of pseudoephedrine.

During the December 29, 2000, execution of Order of Immediate Suspension, DEA investigators seized quantities of pseudoephedrine products which originated primarily from OTC Distribution. A DEA inventory of those products revealed that Respondent had on had 776 cases (144 bottles each) of 120-count bottles, as well as 785 cases (144 bottles each) of 100-count bottles of pseudoephedrine.

Mr. Marquez testified that following the execution of the Order of Immediate Suspension, he along with the Respondent's Operations Manager and Warehouse Manager respectively undertook a physical recount of Respondent's inventory of pseudoephedrine. The recount revealed that Respondent had 775 cases plus 139 bottles (120-count), and 786 cases of 100-count bottles on hand. These numbers were in keeping with the Respondent's computerized inventory. While the recount totals apparently did not include additional bottle quantities of pseudoephedrine that Mr. Marquez subsequently testified were under seal, on June 9, 2001, the Respondent contracted with RGIS (RGIS) Inventory Specialist, a firm that specializes in inventories. The inventory conducted by RGIS revealed that Respondent had on hand 776 cases (144 bottles each) of 120-count bottles of pseudoephedrine, 785 cases plus 139 bottles of 100-count pseudoephedrine, as well as 88 cases of product known as ''Action Blister.''

The Government also presented evidence regarding visits by DEA investigators to various customers of the Respondent that conducted business in Florida and other parts of the United States. One such visit was initiated after Mr. Marquez sought from DEA information on a potential customer, Abdin International Tobacco (Abdin), Abdin, a DEA-registered list I chemical distributor located in vicinity of Orlando, Florida, sought to purchase pseudoephedrine from the Respondent in or around early 2000. DEA's investigation revealed that Abdin sold list I chemical products primarily to convenience stores.

Investigator Solar verified Abdin's registration status with DEA and so informed Mr. Marquez. Shortly thereafter on May 16, 2000, Respondent sold to Abdin 100 cases of pseudoephedrine (144 bottles of 120 sixty milligram tablets) for $116,000. On June 1, 2000, the Respondent sold another 100 cases of pseudoephedrine (144 bottles of 120 sixty milligram tablets) to Abdin for $104,400, which was paid by bank draft. On September 21, 2000, the Respondent sold an additional 50 cases of pseudoephedrine

(144 bottles (120-count) of sixty milligram tablets) to Abdin. This particular order was picked up by Abdin's owner who in turn paid $50,040 in cash for the order.

Investigator Soler testified that the above transactions were suspicious. He based his conclusion on the quantity of product, which Investigator Soler found to be ''very large,'' that Mr. Abdin picked up the product from the Respondent's facility, and that one of the orders was paid for in cash. There is no evidence in the record that the Respondent ever reported any of these transactions to DEA as suspicious.

During his testimony, Mr. Marquez conceded that the owner of Abdin paid cash for fifty cases of pseudoephedrine on September 21, 2000. Mr. Marquez explained, however, that the merchandise was supposed to be paid for with a cashier's check, but Abdin's owner arrived at Respondent's facility early open morning representing that he had not had time to go to the bank. Mr. Marquez testified that he was further informed by Mr. Abdin that the latter had cash from his sales the previous day to cover the purchase, and as a result, Mr. Marquez accepted the cash payment.

Judge Bittner concluded that ABdin's cash payment to the Respondent of more than $50,000 for the fifty cases of pseudoephedrine on September 21, 2000 was suspicious and should have been reported to DEA. The Acting Deputy Administrator concurs with Judge Bittner's finding with respect to this particular transaction, as well as her finding that the suspicious nature of the transaction was not necessarily related to the owner of Abdin picking up the order from Respondent's warehouse.

DEA Diversion Investigator Arthur Fierman-Rentas of the Tampa District Office testified that on May 29, 2001, he visited five convenience stores in the Tampa area which according to Respondent's invoices, purchased pseudoephedrine from the Respondent at various periods between 1999 and 2000. According to Investigator Fierman-Rentas, none of the five stores had any list I chemical products on display as of the date of his visit.

One of the establishments visited by Investigator Fierman-Rentas was Ali's West Indian African and American (Ali's) which purportedly purchased thirty-nine cases of pseudoephedrine from the Respondent between 1999 and 2000. Investigator Fierman-Tentas testified that upon his arrival at that location, Ali's former premises were occupied by an establishment with the business name Third World Grocers. The clerk present at the location informed investigator Fierman-Rentas that Ali's had gone out of business three years earlier. The clerk further stated that he had never heard of the Respondent, his store had no record of transactions involving listed chemicals, and stocked no listed chemical products. Nevertheless, evidence adduced at the hearing revealed that Respondent maintained a file folder for Ali's which contained an address sheet, a Department of Revenue certificate, and at least one order form dated February 14, 2000. The order form bore the customer's name, address and information that 576 bottles of pseudoephedrine were ordered at a price of $2,016 plus $50 shipping.

Investigator Fierman-Rentas also visited Main Grocery, a Tampa area grocery-convenience store, which purportedly purchased forty-one cases of pseudoephedrine from the Respondent between 1999 and 2000. The owner of Main Grocery told Investigator Fierman-Rentas that he had owned the store since March 2001, had never heard of Respondent, and had no invoices from Respondent available. It appears from the record that the Respondent had discontinued its sale of pseudoephedrine to Main Grocery prior to its change of ownership.

DEA's investigation further disclosed that during 1999 and 2000, the Respondent sold forty-five cases of pseudoephedrine in Super Food Supermarket, a convenience store located in Tampa. Investigator Fierman-Rentas testified however, that the location Respondent listed for Super Food Supermarket was occupied by an establishment with the business name, Y & S Supermarket. The individual present informed DEA investigators that he had owned the store since February 10, 1999, but he had no invoices from Respondent available, and did not know if Respondent had sold pseudoephedrine to the store.

Investigator Fierman-Rentas also testified to his visit of Flamingo Food Mart. The store manager was not present at the time of the inspection, but the clerk at that location agreed to assist the investigator by telephoning the store manager. When subsequently contacted, the store's manager informed DEA personnel that he had never heard of Respondent, did not have any invoices of transactions with the Respondent and did not sell list I chemicals. Investigator Fierman-Rentas also asked the clerk at Rainbow Food Place Number 2 to telephone the store manager, who was not present at the time of the inspection. That store's manager subsequently informed Investigator Fierman-Rentas that his bookkeeper had all his invoices and he could not remember whether or not the store had bought list I chemical products from Respondent. A subsequent visit to Rainbow Food Place Number I yielded similar results, where the clerk informed Investigator Fierman-Rentas that the owners of the store had been killed the previous year, that there were no invoices of transactions involving the Respondent, and that he had never heard of Respondent.

Senior Diversion Investigator Ira Wald, also of the Tampa District Office testified that on May 24, 2001, he visited seven additional stores in Florida that according to Respondent's records, were customers for pseudoephedrine products: Georgia discount Store, Cedar Market, Quick Trip Number 1, and Stop 1 in St. Petersburg, Quick Trip Number 2 in Largo, Munchee's No. 101 in Clearwater, and Munchee's No. 102 in Dunedin.

DEA's investigation revealed that the Respondent supplied Georgia Discount Store with forty-three cases of pseudoephedrine between 1999 and 2000. While at the location for that customer, Investigator Wald spoke to a clerk, who said that he had heard of Respondent but had no records. Although the sign on the store read ''Georgia Meat Market,'' Respondent's invoices listed the name of the store as ''Georgia Discount Store.'' While list I products displayed on the shelves of the store were of the brand-name variety containing thirty-milligrams of pseudoephedrine per dosage unit, there were no products with lot numbers corresponding to those on Respondent's invoices for this customer. Additional testimony from a witness for the Respondent revealed that this customer specialized in the sale of meat products.

DEA's investigation revealed that between 1999 and 2000, the Respondent supplied Cedar Market, a grocery store, with thirty-nine cases of pseudoephedrine. According to Investigator Wald, the manager of that location claimed that he had not heard of Respondent, there were no invoices, and there was no pseudoephedrine or other list I chemical products on display.

DEA's investigation revealed that between 1999 and 2000, the Respondent supplied Quick Trip Number 1, a gas station, with forty-one cases of pseudoephedrine. Investigator Wald found the pseudoephedrine product ''Mini-Thins'' in stock, but the lot numbers did not correspond to those on Respondent's invoices. The clerk present did not have any invoices and had not heard of Respondent.

With respect to Quick Trip Number 2, a convenience store, DEA's investigation

revealed that between 1999 and 2000, the Respondent supplied this establishment with forty-one cases of pseudoephedrine. A review of the record regarding this customer, as well as a review of Respondent's sale of pseudoephedrine to Munchee's 101 (to which the Respondent supplied thirty-five cases of pseudoephedrine between 1999 and 2000), revealed that there were no list I chemical products on display, the respective clerks had never heard of Respondent and did not have invoices of any transactions involving the Respondent. Likewise, according to Investigator Wald, Munchee's No. 102, a convenience and grocery store that was supplied thirty-nine cases of pseudoephedrine by the Respondent between 1999 and 2000, had no list I products in stock. The clerk at Munchee's 102 informed DEA personnel that he was not the manager, had not bought merchandise from, or ever heard of Respondent, and did not have any invoices for its products.

With respect to Stop 1, a grocery store, DEA's investigation revealed that between 1999 and 2000, the Respondent supplied this establishment with thirty-seven cases of pseudoephedrine. Investigator Wald testified that Stop 1 carried a brand name product containing pseudoephedrine, but the clerk had never heard of Respondent and did not maintain invoices for its products.

DEA Diversion Investigator Deborah George of the agency's Orlando, Florida office, testified to her visits to the following Orlando-area customers of the Respondent on June 1, 2001: Jules Gifts, Inc., La Belle Creole, and S & A Gift Shop in Orlando, and Publix Supermarket, Fresh Supermarket & Gifts, Bargain Zone Grocery, and Little Bargain Zone #2 in Kissimmee. At the time of her visits, Investigator George did not identify herself as a DEA investigator or speak to owners or managers, but looked in the stores to see whether Respondent's listed chemical products were on the shelf.

Investigator George testified that a review of the Respondent's records revealed a customer known as Jules Gifts; however, a subsequent check of that location revealed that the business was a residence. Mr. Marquez acknowledged that the address listed on Jules Gifts' Florida Department of Revenue registration was the owner's residence, but that Mr. Tekelewold assured him that he had been to the store and made sure that the product was going to a real retail business. Mr. Marquez also acknowledged that there was no document in the customer file indicating a different shipping address and that a United Parcel Service record of shipment that Respondent offered into evidence showed the residential address as the location where pseudoephedrine products were eventually shipped.

Investigator George testified to her visit to the location of a customer listed in the Respondent's records as La Belle Creole. It was later determined that La Belle Creole was a restaurant named Havana's #2. Investigator George did not go into the restaurant. Mr. Tekelewold testified that La Belle Creole was a grocery store and a customer of the Respondent until July 2000.

Investigator George testified that the address listed for S&A Gift Shop was inside a Sheraton hotel, and that she did not see any of Respondent's products in the shop. Mr. Tekelewold testified that the gift shop had been a Respondent customer until July or August 2000. Investigator George further testified that she did not see any of Respondent's listed chemical products in the Publix Supermarket, Little Bargain Zone #2, or Fresh Supermarket & Gifts, although she did see listed chemical products from other vendors at these locations. At Bargain Zone Grocery, Investigator George saw one display of individual packages of Max grand pseudoephedrine with six tablets in each package. Investigator George testified that she drove past Sonia's Deli & Grocery in Kissimmee, but did not enter the premises. Investigator George further testified that she did not visit various other Respondent customers at six additional locations because of information that persons associated with those establishments were under indictment.

As part of its investigation of the Respondent's distribution practices, DEA also sought information about the company's shipment of pseudoephedrine products to customers in the State of New Jersey. To that end, on June 7, 2001, Diversion Investigators Suckcha Tharp and Andrew Breiner of DEA's Newark, New Jersey field office visited the Middle Eastern Market, the Al-Madena Deli, and the Neighborhood Supermarket, all in Paterson, New Jersey. These visits were initiated to corroborate information in the Respondent's invoices that these entities had been Respondent's customers between March and July 1999. The following day, the investigators visited the Getty Deli and the S&M Golden Mini-Mart, also in Paterson, for the same purpose. The owners of the Middle East Food Market and Al-Madena Deli told the investigators that they had acquired the stores after 1999, but had never purchased any of Respondent's products. The manager of the Neighborhood Supermarket said that his family had owned the store since 1982, but had never purchased any of Respondent's products.

Similarly, the owners of the Golden Mini-Market and the Getty Deli both told the investigators that they had owned their respective stores for five years, but had never purchased any products from Respondent and did not have any in the store. A salesclerk of the Big Apple Meat Corporation further informed the investigators that the store had not purchased any products from Respondent in the year and a half that he had worked there. The investigators did not see any list I chemical products at any of the visited stores.

Despite the above evidence suggesting that the Respondent had not engaged in regulated transactions with the above New Jersey-area customers, Mr. Marquez testified, and Respondent's records confirmed, that Respondent sold to six convenience stores in Paterson: Middle East Food Market, Al-Madena Grocery, Getty Deli, Big Apple Market, S&M Golden Mini-Market, and Neighborhood Supermarket, along with the Four Corner Store in Passaic, New Jersey. Specifically, the Respondent's invoices indicated that it sold 576 100-count bottles of 60-milligram pseudoephedrine (Revive brand product) to Middle East Food Market in April, May, and July 1999; four boxes of Revive 60 milligram to Al-Madena Grocery Deli in April, May, and July 1999; four boxes of Revive 60 milligram to Getty Deli in April, May, and July 1999; four boxes of Revive 60 milligram to Big Apple Meat Corporation in March, May, and July 1999; four boxes of Revive 60 milligram to S&M Golden Mini Market in March, May, and July 1999; and four boxes of Revive 60 milligram to Neighborhood Supermarket in March and May 1999. Mr. Ahmad also obtained written statements from three of Respondent's Paterson customers in which the customers stated in essence, that despite previous information provided to DEA investigators, they had in fact purchased list I chemical products from the Respondent at various times.

Evidence was also presented at the administrative hearing regarding the Respondent's sale of list I chemical products to customers in the State of Michigan. Diversion Investigator Barbara Dobric of DEA's Detroit office, testified that in late May and early June 2001 she along with Diversion Group Supervisor Jim Geldhof visited twenty-three retail customers of Respondent in the metropolitan Detroit area to ascertain whether they had purchased

pseudoephedrine from Respondent. Among the retail establishments visited by DEA investigators were Dollar City Plus, a dollar store, and Duke's Oil, a gas station in Detroit. These retailers informed DEA that they had never dealt with Respondent because they ordered only from distributors in Michigan.

DEA investigators learned from another purported customer, Woodward and Harmon Mini Mart in Highland Park, that the store had been at the same location for four years, but had never dealt with Respondent and did not sell list I chemical products. While at the location of yet another purported customer, Dollar Value in Redford, the owner told Investigator Dobric that he did not know if he had ever bought from Respondent and he had no invoices that would refresh his recollection. Investigator Dobric testified that the owners of two additional establishments did not have invoices of any purchases of list I chemicals, and therefore, could not remember whether or not they had purchased these products from the Respondent. One customer, a gasoline station located in Oak Park, informed Investigator Dobric that it had purchased product from Respondent and provided her with copies of invoices.

Investigator Dobric also testified that DEA's inspections of ten additional customers of the Respondent, comprised primarily of gasoline stations, mini mart/convenience stores, and tobacco shops, revealed that they had in fact purchased list I chemical products from the Respondent, but could produce no invoices. Five other customers informed Investigator Dobric that their establishments had undergone name and/or ownership changes, and therefore could not provide information about prior owners. One establishment, the Tobacco and Cigar Shop, was vacant.

The Government also presented evidence that sought to compare the Respondent's marketing of its bottled pseudoephedrine products and the marketing and distribution of Sudafed and other list I chemical products by nationally recognized pharmaceutical companies. As part of its evidentiary presentation, the Government introduced into evidence a declaration dated October 18, 2000, from Susan O'Connor, Pfizer's product manager for Sudafed for the two years prior to August 2000. Evidence presented during the hearing showed that since approximately 1997, Sudafed had been sold only in blister packages; prior to that time it was also sold in bottles. Ms. O'Connor stated that until 1997, Sudafed was available as a 60-mg. tablet, but the product was discontinued because of low demand for it.

Ms. O'Connor testified that Pfizer sold the 30-milligram strength product in packages of 24, 48, or 96 tablets, and delayed-released formulations of 120 milligrams in packages of ten and twenty caplets and of 240 milligrams in packages of five and ten caplets. She further stated that according to data from Information Resources, Incorporated, 258,260,252 Sudafed 30-milligram tablets, 39,551,717 Sudafed 120-milligram delayed-release caplets, and 6,594,430 Sudafed 240-milligram delayed-release caplets were sold at retail in the period August 1999 through April 2000. According to her estimates, Pfizer sends approximately eighty-percent of its shipments directly to retailers and sends the remaining shipments to various wholesalers. Among Pfizer's major customers are drug chains, grocery chains, and mass merchandisers such as Wal-Mart, Target, Walgreen's, etc., and that non-retailer shipments are to ''reputable wholesalers.''

With respect to comparisons between Pfizer's sale of pseudoephedrine products, and those of Pfizer's known competitors, Ms. O'Connor stated that she first heard of OTC Distributors from DEA and that, according to information provided to her by DEA, OTC Distributors sold approximately 92,162,540 60-mg. pseudoephedrine tablets between August 1999 and April 2000. According to Ms. O'Connor, ''[i]f a new brand had sales of that amount of pseudoephedrine in grocery chains or other known retail outlets, I am sure that I would have been aware of the brand's existence, since that volume of sales would represent competition for Sudafed.''

The Government also presented testimony from Kara Pollard, product manager for Sudafed at Pfizer, who testified that as of the date of her testimony, the total annual factory dollar sales for Sudafed 30-milligrams were approximately $50 million and the total sales for the entire Sudafed line would be about $190 million. Ms. Pollard also testified that year-to-date sales for 2001 had increased about seventeen percent over the same period the prior year due to a recall of products containing phenylpropanolamine. Ms. Pollard further testified that the average retail price varies among the more than twenty-four Sudafed products according to the package configuration and the type of retailer. Ms. Pollard characterized chains such as Wal-Mart as ''self-distributing,'' i.e., retail chains that buy product directly from manufacturers and store it in their own warehouses. It was Ms. Pollard's conclusion that sales to convenience stores are not a significant percentage of Pfizer's pseudoephedrine sales.

The Government also introduced into evidence a declaration from Irene Day, project manager for over-the-counter cough and cold medications at L. Perrigo Company (Perrigo). Ms. Day testified that Perrigo is the largest manufacturer of over-the-counter pharmaceutical products for the store brand market, that one of its products is a nasal decongestant which contains as its sole active ingredient thirty milligrams of pseudoephedrine and that Perrigo does not manufacture a single-active-pseudoephedrine product that contains sixty milligrams of pseudoephedrine. Ms. Day also testified that Perrigo sells its pseudoephedrine products in blister packs containing 24, 48, or 906 tablets, and that because these packages each contain less than three grams of base pseudoephedrine, they meet the safe harbor provision of the Methamphetamine Control Act of 1996. Ms. Day further testified that for the period August 1999 through April 2000, Perrigo sold a total of 299,329,130 tablets of thirty-milligram single-active pseudoephedrine, that approximately fifty percent of Perrigo's shipments go to its retail customers' distribution centers, that most of the remainder go to drug or food wholesalers, and that Perrigo ships to a few small retail customers directly.

The Government also presented an expert witness in the area of statistical analysis of convenience stores and their sale of pseudoephedrine. Jonathan Robbin, a consultant in marketing information systems and databases, tesified on behalf of the Government as an expert in statistical anaysis and quantitative marketing research. With respect to the expert statistical analysis offered by Mr. Robbin, the Deputy Administrator adopts the following Findings of Act, as set forth in Judge Bittner's Opinion and Recommended Ruling:

Mr. Robbin analyzed data from the United States Economic Census, which, among other things, includes information on the kinds of goods that different types of retail stores sell. The Economic Census is undertaken by the United States Department of Commerce every five years, and elicits from every business establishment in the United States information that includes, among other things, the business's operations, size, gross income, organization, and number of employees. Businesses are required to respond to the Economic Census and Mr. Robbin testified that the response rate is about ninety percent. The Census Bureau processes the data

collected in the census and publishes various reports reflecting that data. The Census Bureau makes aggregate data, tabulated by various criteria, available and also performs tabulations for specific purposes.

Mr. Robbin further analyzed data from the Syndicated Research Study by Mediamark Research, Inc. (Mediamark), which analyzes consumer buying behavior, information from Information Resources International, which tracks data from the bar scanners of retail stores, and a report from the National Association of Convenience Stores (NACS). The NACS membership consists primarily of large convenience store chains, but its survey included nonmember stores that receive Convenience Store News, a trade publication that is distributed without charge to stores in the industry. Mr. Robbin also reviewed invoices reflecting Respondent's sale of pseudoephedrine to various customers. Mr. Robbin testified that the objective of his study was ''to be able to say with some certainty whether or not [pseudoephedrine] was being distributed in a manner that was congruent with normal marketing practice and meaningful from a commercial point of view. * * *''

Mr. Robbin defined ''convenience store'' as ''a store that sells goods to be consumed on the premises or to be consumed shortly after they are bought,'' and includes nearly 30,000 convenience stores in the United States that do not have gasoline pumps and another 70,000 that have them. Mr. Robbin testified that the average convenience store occupies about 1350 square feet, has revenues of between $600,000 and $800,000 per year, and employs from two to five people. Mr. Robbin further testified that ninety percent of a convenience store's customers come from within a ten mile radius, and half of them come from within three miles of the store. Mr. Robbin also noted that convenience stores do not have large stockrooms and therefore do not carry a large inventory of diverse products.

Mr. Robbin used various data ''to establish a reasonable expectation'' of how much pseudoephedrine a convenience store would sell; calculated ''a reasonable dollar volume of sales to consumers of decongestant tablets containing pseudoephedrine,'' given how much of this product Respondent sold to certain convenience stores in Florida; and then contrasted how much a store would reasonably be expected to sell with the quantities that Respondent's customers purchased from it.

Mr. Robbin testified that data from the 1997 Economic Census showed that drugstores, supermarkets, and discount stores accounted for 92.3 percent of all sales of non-prescription medications, and convenience stores with and without gasoline pumps accounted for about 1.75 percent and less than one percent, respectively, of sales of these products. The National Association of Convenience Stores reported that beauty and health care products comprised 1.31 percent of in-store sales in convenience stores in 1999.

In the Economic Census, Merchandise Line (ML) 160 consists of all health and beauty aids, including both prescription and non-prescription drugs, vitamins, and minerals. Merchandise Line 162 is a subset of ML 160, and includes a variety of over-the-counter items such as headache remedies, eye drops, allergy remedies, and cough drops, as well as decongestants such as pseudoephedrine. The products in ML 162 represent 6.5 percent of the dollar sales of ML 160. Mr. Robbin testified that the Economic Census form for convenience stores attached to gasoline stations does not include ML 162, presumably because few such retailers sell over-the-counter medications, so he imputed what convenience stores' sales of ML 162 would be from the data relating to ML 160; Mr. Robbin concluded that 0.4 percent of sales by convenience stores with gasoline pumps are of non-prescription drugs. Mr. Robbin further testified that about 10,000 convenience stores without gasoline pumps sell non-prescription medicines, and about 23,000 of the convenience stores with gasoline pumps sell these products. Mr. Robbin testified that the Census Bureau had not observed any sales of ML 162 by any florist, novelty and gift store, or liquor store.

Mr. Robbin analyzed data from Mediamark to compare the percentage of consumers who purchase non-prescription drugs from drugstores, department stores, grocery stores, and discount stores, to the percentage of consumers who purchase these items from convenience stores. Specifically, Mr. Robbin used Sudafed as a surrogate for Respondent's product to indicate how many consumers of pseudoephedrine purchased it at a convenience store rather than at one of the more traditional retailers. Mr. Robbin concluded that seven million households, or 4.92 percent of all purchasers of non-prescription drugs from drug, department, grocery, or discount stores, had purchased Sudafed in 2000, and that 4.35 percent of all purchasers who bought over-the-counter medications at a convenience store bought Sudafed. Mr. Robbins further concluded that 0.21 percent of adults who shopped at convenience stores purchased Sudafed. Mr. Robbin analyzed data from Information Resources, Incorporated as to monthly sales of Sudafed and determined that Sudafed represented 1.14 percent of the sales of ML 162. Mr. Robbin then estimated that equal amounts of generic store brands and of two competitive brands of pseudoephedrine, Contac and Actifed, were also sold, so that overall sales of pseudoephedrine represent 4.56 percent of the sales of items in ML 162. Mr. Robbin however qualified this estimate in that he thought it overstated the amount of pseudoephedrine sold.

Mr. Robbin further testified to a formula that he employed to determine the retail price of goods by dividing the wholesale price by one minus the gross margin, and that in-store margins for the convenience store industry were 31.2 percent in 1998 and 30 percent in 1999. Thus, the expected retail price would be the wholesale price divided by .7. Mr. Robbin then reviewed various data with respect to sales of pseudoephedrine, including invoices for 212 of Respondent's Florida customers, and he estimated that the monthly sales of pseudoephedrine by various types of retailers in 1999, as summarized by the following table:

| Kind of Business | Pseudoephedrine Sales |
|---|---|
| Supermarkets, grocery stores | $618 |
| convenience stores | 27 |
| specialty food stores | 34 |
| pharmacies, drug and proprietary stores | 663 |
| cosmetics, beauty supplies and perfume stores | 21 |
| other health and personal care stores | 208 |
| department stores | 1,921 |
| electronic shopping and mail order stores | 3,376 |
| gasoline stations with convenience stores | 32 |

Mr. Robbin assigned each of Respondent's customers to a retail category (e.g., grocery store, convenience store, convenience store with gasoline pump). These classifications were assigned based on the name of the customer (if the name included ''grocery store,'' he assumed the customer was a grocery store), photographs that the Government provided of some stores, and information from sources of commercial addresses. Mr. Robbin testified that probably half of the customers of Respondent that he listed as grocery

stores (which would be expected to sell more pseudoephedrine than convenience stores do) were in fact convenience stores.

Mr. Robbin then estimated for each customer how much pseudoephedrine it would be expected to sell per month based on the estimates described above, and calculated how much it did sell based on how much it purchased from Respondent and assuming that the store marked up the product thirty percent and sold all that it purchased. For example, Mr. Robbin noted that BP Super Stop, presumably a convenience store that sold gasoline, purchased $22,428 of pseudoephedrine from Respondent over a fourteen-month period, or $1,602 per month. With a thirty percent markup, retail pseudoephedrine sales would have amounted to $2,289, but Mr. Robbin's analysis of Economic Census and other data predicted that this customer would have had pseudoephedrine sales of $32.41 per month, for an index of actual to expected sales of 70.6.

Mr. Robbin testified that he calculated Z statistics, standard deviates measured in terms of standard deviations; according to Mr. Robbin, ''it tells us in standard deviant units how far we are from the average.'' More simply, Mr. Robbin testified that he '';* * * would not expect a convenience store to sell this amount of pseudoephedrine under any circumstances in the normal sale of these goods through the channels that the Census and other sources tell us these goods are sold.''

Mr. Robbin noted that Americans consume, on average. 147 cold pills per person per year, so that a bottle of Respondent's pseudoephedrine product would be almost a year's supply for the average consumer. According to Mr. Robbin, ''[i]t is inconceivable that people will come in and out of these stores and regularly month to month [buy] a year's supply of the drug. * * *''

With respect to Respondent's grocery store customers, Mr. Robbin testified that the index of actual to expected sales was considerably lower, most ranging from 2.4 to 4.3, but sill more than two standard deviations to the mean. Mr. Robbin testified that 1.96 standard deviations of the mean in the two-tailed test of significance would encompass 95 percent of all cases under the normal curve, and that three standard deviations would encompass 99 percent of cases.

Mr. Robbin emphasized that the Economic Census represents one hundred percent of the data, not samples, and that aggregate data has a lower variance than would a database of individual establishments. Because Mr. Robbin did not have access to the variance of individual stores, he asked the Census Bureau for a tabulation of individual records. Mr. Robbin testified that the Census Bureau tabulation ''gave me condifence * * * in making the statement that these data are reflecting reality.'' Mr. Robbin stated in his report:

> In summary, most of the stores to which [Respondent] has supplied pseudoephedrine products have a very small or no likelihood of selling them over the counter to consumers seeking remedies for nasal congestion from allergies, colds or other conditions. This conclusion is strongly supported by data from the United States 1997 Economic Census and current observations of two independent marketing information companies, Mediamark Research, Inc., and Information Resources International.
>
> Mr. Robbin further testified that his finding is that the goods that [Respondent] has provided to these stores are not following the normal channel of distribution for goods of this kind, that they are going to a nontraditional market that is not known to sell any substantial or meaningful quantities of these goods, and that there is no logical explanation in common marketing practice to explain this phenomenon.

Mr. Marquez testified that he disagreed with Mr. Robbin's analysis. According to Mr. Marquez, small independent convenience stores do not provide data to researchers, the owners of such stores may well fail to fill out the Economic Census forms or fill them out inaccurately, and as a result, there are no statistics on what these stores sell. Mr. Marquez further testified that the smallest quantity of any product Respondent would sell to a store would be $800 to $3,000 per week, and that a retail establishment would not carry a product that did not produce more revenue than $27 per month. Mr. Marquez further testified that he believed that Respondent's customers were capable of selling pseudoephedrine under the conditions that Respondent had established, and that ''we checked the stores and made sure they were selling the product.''

Mr. Marquez further testified that he did not question why a convenience store would be purchasing so much pseudoephedrine every month ''because they wouldn't be buying it if they wouldn't be selling it.'' Asked on cross-examination who he thought would buy a bottle of 120-count 60-milligram pseudoephedrine for $9.95 or $19.95, Mr. Marquez responded, ''I've seen it, you know, when I go the 7–11 or places. It's mostly blue collar workers, people that work out on the street or work out in the hot sun, and they've got problems breathing, or it's too humid and people need that kind of medication.'' Mr. Marquez testified that it was ''[n]ot at all'' unusual for Respondent to sell 576 bottles of 60-count 60-milligram pseudoephedrine to retail stores. Mr. Marquez concluded that he did not believe that most Sudafed and pseudoephedrine products are not sold in convenience stores, and that the information in the NACS State of the Industry Report came from national chain stores, not small family-owned convenience stores.

As noted above, and pursuant to 21 U.S.C. 824(d), the then-Deputy Administrator issued an immediate suspension of the Respondent's DEA Certificate of Registration. While the above cited evidence provides ample grounds for an immediate suspension pursuant to section 824(D), these grounds also provide the basis for the revocation of the Respondent's DEA Certificate of Registration. *See Yemen Wholesale Tobacco and Candy Supply, Inc.,* 67 FR 9997, 9998 (2002).

Pursuant to 21 U.S.C. 824(a), the Acting Deputy Administrator may revoke a registration to distribute list I chemicals upon a finding that the registrant has committed such acts as would render such registration under section 823 inconsistent with the public interest as determined under that section. Pursuant to 21 U.S.C. 823(h), the following factors are 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 Acting 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., Energy Outlet,* 64 FR 14269 (1999). *See also Henry J. Schwartz, Jr., M.D.* 54 FR 16422 (1989).

As an initial argument, the Government asserted that Respondent's conduct in distributing listed chemical products to convenience stores under

the management of Mr. Marquez are sufficiently apparent to make out a violation under 21 U.S.C. 841(c)(2). The Government further outlined the primary requirement of section 841(c)(2) that must be proven by a preponderance of evidence: the knowing or having reasonable cause to believe that the listed chemical will be used to manufacture a controlled substance. In support of a finding under the above provision, the Government argued that the Respondent's main business was purportedly the distribution of candy and snacks, yet, in 2000, the company purchased large quantities of pseudoephedrine ''in anticipation of an unavailability or allocation of listed chemical product.'' The Respondent argued in response that there are no statutory restrictions under the Controlled Substances Act with respect to ''attempts'' to obtain list I chemical products, and the Government has failed in its burden of proof in establishing what constitutes ''excessive'' ordering.

The Government also argued that the ''traditional'' market serves legitimate need with 30 mg. pseudoephedrine products packaged in blister packs and sold predominantly at pharmacy chains, supermarkets and discount stores. This, the Government contrasted with what it characterized as the ''non-traditional'' market where ''products are packaged in 60 mg. large count bottles and are sold in convenience stores or other places where such products are not usually sold.'' The Government concluded that small convenience stores are a source for diversion of listed chemical products. Conversely, the Respondent argued, *inter alia,* that the occurrence of diversion cannot, standing alone, rise to the level of a revocation action since ''all persons in the regulated trade are susceptible to diversion and, at various times, have fallen victim to it.''

The Government further argued that in keeping with the holding in *United States* v. *Prather,* 205 F.3d 1265 (11th Cir. 2000), where the defendant was convicted of, among other things, distributing pseudoephedrine knowing of having reasonable cause to believe that it would be used to manufacture a controlled substance, the Respondent as the defendant in *Prather,* had ''reasonable cause to believe'' that its listed chemical products would be used to manufacture a controlled substance.

In recent DEA decisions, the agency has found that gas stations and convenience stores (which the Government argues are part of the ''non-traditional'' market) constitute sources for the diversion of listed chemical products (*See, e.g., Sinbad Distributing,* 67 FR 10232, 10233 (2002); *Xtreme Enterprises, Inc.,* 67 FR 76195 (2002); *K.V.M. Enterprises,* 67 FR 70968 (2002)). However, in deference to my predecessor's ruling in *Mediplas Innovations* (67 FR 41256 (2002) (''Mediplas'')), a finding regarding convenience stores a conduits for the diversion of listed chemicals does not necessarily translate to a finding regarding the existence of the so-called ''traditional'' versus the ''non-traditional'' markets for products containing ephedrine and pseudoephedrine. Rather, in *Mediplas,* the then-Deputy Administrator found that there was little probative value to such evidence, and the probative weight of evidence regarding traditional and non-traditional markets ''is minimal without some form of further extrinsic evidence to support these arguments.'' *Id.* at 41264. The Acting Deputy Administrator notes further, my predecessor's conclusion that a registrant's sale of large quantities of list I chemicals do not, in and of themselves, demonstrate that the chemicals may be diverted. *Id.*

In the instant proceeding however, the Acting Deputy Administrator finds that the Government has met the test outlined in *Mediplas,* and established through extrinsic evidence the typical market for listed chemical products. In keeping with this finding, the Acting Deputy Administrator concurs with Judge Bittner's conclusion that the Government met the *Mediplas* evidentiary requirement by showing that Respondent sold pseudoephedrine to customers that did not have a reasonable expectation of being able to resell the product to a legitimate customer base. Specifically, the Government presented a relevant comparison analysis involving the marketing and sale of bottled pseudoephedrine products to a relatively small market by OTC Distribution (a supplier of listed chemicals to the Respondent) versus that of nationally recognized pharmaceutical manufacturers and distributors of those products (i.e., Pfizer and the L. Perrigo, Company). The Acting Deputy Administrator also finds telling, the testimony of Pfizer and Perrigo representatives that neither were aware of OTC Distribution as a possible competitor.

More persuasive however, was the testimony and documentary evidence prepared by the Government expert in statistical analysis, Jonathan Robbin. In arriving at a finding regarding Mr. Robbin's testimony, the Acting Deputy Administrator has given due consideration to the Respondent's contentions that Mr. Robbin's report, among other things, contained selective sales data regarding Sudafed products, did not properly assess the breadth of the market for Sudafed products, and that convenience stores and grocery stores can serve the same needs as large grocery stores in the absence of large chain establishments.

Notwithstanding these arguments, the Acting Deputy Administrator nevertheless finds compelling Mr. Robbin's conclusion of the unlikelihood that convenience stores would sell more than $27.00 worth of pseudoephedrine per month to consumers purchasing decongestant products, as purportedly sold by Respondent's customers. The Acting Deputy Administrator further credits Mr. Robbin's finding regarding the inconceivability of customers purchasing a year's supply of list I chemical products from convenience stores and related establishments on a monthly basis.

The Acting Deputy Administrator also finds persuasive the conclusion of Mr. Robbin that pseudoephedrine products supplied by the Respondent to its customers did not follow the normal channel of distribution for goods of this kind. This finding is given further credence when one considers the quantities of pseudoephedrine the Respondent sold to its convenience store customers and the exorbitant price some of these customers were willing to pay the Respondent for those products. The Acting Deputy Administrator finds that the compelling nature of Mr. Robbin's market study cast doubt on the legitimacy of the Respondent's regulated transactions with a substantial segment of its customers, and brings some context to matters relating to the diversion of the Respondent's listed chemical products.

On a related note, the Acting Deputy Administrator finds that Mr. Marquez was made aware through the DEA pre-registration process that pseudoephedrine is subject to diversion. Nevertheless, despite the variety of non-list I products purportedly sold by the Respondent, the purchase of goods by its customers were limited to pseudoephedrine. Notwithstanding Mr. Marquez's testimony that it was not unusual to sell 576 bottles of 60-count, 60 milligram pseudoephedrine to retail stores (at a retail price as high as of twenty dollars a bottle), and in light of market analysis of the Government expert regarding the expected sale of these products, the Acting Deputy Administrator finds that there is justified concern over the Respondent's sale of large quantities of listed chemicals to its customers. Therefore,

the Acting Deputy Administrator concurs with the finding of Judge Bittner that the Respondent had reason to believe that the pseudoephedrine it sold, particularly in the quantities sold to its convenience store customers, was likely to be diverted. *See, MDI Pharmaceuticals,* 68 FR 4233 (2003).

With respect to the factors enumerated under 21 U.S.C. 823(h), and in addition to the analysis outlined above, the Acting Deputy Administrator finds that factor one, maintenance of effective controls against diversion, is further applicable to the Respondent's sale of pseudoephedrine products to Abdin. For purposes of 21 U.S.C. 830(b)(1), an uncommon method of payment, such as cash, renders the sales of pseudoephedrine suspicious. *United States* v. *Grab Bag Distributing, et al.,* 189 F. Supp. 2d 1072 (2002); *United States* v. *Akhtar,* 95 F. Supp. 2d 668 (S.D. Tex. 1999) (a defendant admitted that four ephedrine transactions were unusual because they were made in cash and because they were for progressively larger quantities of ephedrine). Such transactions are required to be reported to DEA pursuant to 21 CFR 1310.05(a)(1) (2000). As noted in Judge Bittner's Opinion and Recommended Ruling, Mr. Abdin paid more than $50,000 in cash for fifty cases of pseudoephedrine purchased from the Respondent on September 21, 2000. The Acting Deputy Administrator therefore adopts Judge Bittner's conclusion that this cash payment made the transaction suspicious, and as a result, Respondent should have reported the same to DEA.

With respect to statements of customers regarding their purported purchase of pseudoephedrine from the Respondent, Judge Bittner found the evidence generally insufficient to support the revocation of Respondent's DEA Certificate of Registration under factor one. Specifically, Judge Bittner found that because a period of at least nine months had passed since Respondent sold list I chemicals to these establishments, and the fact that these establishments were under no obligation to maintain records of their dealings with the Respondent, evidence of their failure to account for listed chemical purchases did not support a revocation action involving the Respondent's DEA registration. Judge Bittner found however, that one exception in this regard was the Respondent's shipment of pseudoephedrine to Jules Gifts, Incorporated, an Orlando-based gift shop situated at a residential address, and such shipment supported a finding that the Respondent's continued registration would not be in the public interest.

In keeping with Judge Bittner's finding regarding the overall insufficiency of the customer statements, the Acting Deputy Administrator further notes that many of DEA's interviews were of store clerks (as opposed to store owners), new owners of business establishments with no apparent knowledge of any actions by previous owners, or shop owners who simply could not recall whether there existed a business relationship between their establishment and the Respondent. Moreover, several Michigan area customers informed DEA investigators of their business relationship with the Respondent but could produce no invoices. Therefore, to the extent that these factors were present, evidence regarding customer verifications by DEA investigators were not considered under factor one by the Acting Deputy Administrator in rendering here final decision. Nevertheless, the Acting Deputy Administrator finds that customer verifications of eight other customers are applicable under factor five as outlined below.

With regard to factor two, compliance with applicable Federal, State an local law, the Government argues, in part, that an accountability audit of Respondent's handling of listed chemical products between the date of its registration and July 31, 2000, disclosed a shortage of approximately 98,381 bottles of pseudoephedrine. However, in its Proposed Findings of Fact and Conclusions of Law and Argument, the Respondent argued that the audit contained ''substantial arithmetic errors.'' The Respondent argued in essence that in preparing its audit, the Government did not provide a correct accounting of information contained within Respondent's sales invoices and the Government-prepared summaries of those invoices.

As one example, the Respondent noted that a Government exhibit which consists of sales invoices, as well as a summary sheet for a customer of the Respondent list sales transactions for November 11, 1999, December 15, 1999 and February 21, 2000 as 288 bottles. The Respondent argued however that that actual invoice for these transactions yielded a count of 576 bottles, not 288 bottles as listed on the Government prepared summary. The Respondent used this, as well as other examples to assert that the Government's audit as not reliable.

In her Opinion and Recommended Ruling, and following here review of invoices in evidence for the Respondent's Florida customers, Judge Bittner agreed with the Respondent that there were ''numerous apparent mistakes in the [Government's] compilation.'' In support of her finding, Judge Bittner appended to her opinion a separate compilation of the purchases of pseudoephedrine by the Respondent's Florida customers. Under the ''Comments'' heading of the Appendix, Judge Bittner noted several instances where the compilation of Respondent's purchases prepared by DEA indicates the purchase of 288 bottles, when it appeared from the invoice that purchases were for 576 bottles. As a result of the apparent conflict between the Government prepared summaries, and the information contained on the face of the actual invoices, Judge Bittner concluded that ''the record does not establish the extent of a shortage, if any, and therefore [the Government audit is unreliable].''

On December 19,2002, counsel of the Government filed Exceptions to the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge. In its Exceptions, the Government argues in relevant part, that the audit and computation were conducted by NDIC directly from invoices acquired from Respondent. The Government argued that Investigator Soler took custody of the Respondent's records and sales files and that Government exhibits memorializing sales to specific retailers were prepared by Investigator Soler. The Government further argued that the compilation prepared by Investigator Soler did not include every one of Respondent's customers, and did not form the basis of the audit.

As a general rule, recordkeeping discrepancies involving list I chemicals constitute violations of 21 U.S.C. 830(a) and 842(a)(10) and 21 CFR 1310.03 and 1310.06. *Mediplas* at 41263. The Government asserts that the Respondent violated record keeping provisions by its failure to account for listed chemicals, and thus a finding in support of the revocation of Respondent DEA registration should be made under factor two.

The Acting Deputy Administrator has conducted an extensive review of all relevant evidence regarding the audit, including Government exhibits and the testimony of Investigator Solar. From that interview, it is clear that information on the face of several of the DEA-prepared compilations is not consistent with the actual invoices of Respondent's purchases that the compilations purport to represent. What

is unclear from the record however is whether these incongruous records (the compilations and invoices) were used together in conducting the audit or whether the compilations were excluded from consideration.

What is particularly problematic in determining what credence, if any, should be given to the audit results, is the insufficiency of evidence regarding the methodology used in conducting the audit. The lack of specifics in this regard leaves the matter of the compilations and their impact on the audit results, an open question. Notwithstanding the assertion by the Government that summaries prepared by a DEA investigator did not form the basis of the audit, there is no testimony to that effect in the record. Yet, the Government witness testified to the compilations as part of the DEA's investigation of the Respondent. Under these circumstances, the Acting Deputy Administrator finds the record incomplete with respect to the manner in which the audit was conducted, and unclear as to whether the in consistent information contained within the DEA-prepared compilations played any part in the audit results. Accordingly, the Acting Deputy Administrator adopts the finding of Judge Bittner that the Government-prepared accountability audit and computation are unreliable, and thus, inapplicable to a finding under the factor two analysis enunciated above.

The Acting Deputy Administrator agrees with counsel for the Government that factor two is relevant to the Respondent's failure to report to DEA that a regulated transaction with Abdin included an uncommon method of payment, as required by 21 CFR 1310.05(a)(1). *Aqui Enterprises,* 67 FR 12576 (2002).

With regard to factor three, any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law, there is no evidence in the record that the Respondent or its owners have been convicted of any offenses as contemplated by this provision.

With respect to factor four, past experience in the manufacture and distribution of chemicals, the Acting Deputy Administrator has combined the evidence pertaining to this factor with those contained under factor two, controls against diversion and compliance with applicable law. *See, Service Pharmacy, Inc.,* 61 FR 10791, 10795 (1996).

With regard to factor five, such other factors relevant to and consistent with the public safety, the Acting Deputy Administrator incorporates the matters above into this factor, and finds factor five relevant to a finding that the Respondent's continued registration with DEA would be inconsistent with the public interest.

The Acting Deputy Administrator also finds factor five relevant to customer statements regarding their purported purchase of pseudoephedrine from the Respondent. As noted above, Judge Bittner found that evidence regarding most of these statements was generally insufficient to support the revocation of the Respondent's DEA Certificate of Registration. The Respondent added that the actions or inactions of the Respondent's customers to fulfill the Government's investigative demands cannot be the basis for revocation of the Respondent's registration.

The Acting Deputy Administrator agrees with the Respondent's assessment that its customers were under no obligation to assist DEA investigators or produce records of regulated transactions with the Respondent. However, the Acting Deputy Administrator also recognizes the importance of the DEA investigative process, particularly as it relates to verification of customers who purchase list I chemicals from DEA-registered distributors. These regulatory inspections serve a vital role in protecting the public health and safety, and are of particular importance in helping to stem the diversion of listed chemical products. The importance of the DEA investigative process, and specifically the verification of customer information, has been highlighted in prior DEA rulings; the agency has made findings under factor five where DEA investigative personnel were unable to corroborate customer information of handlers of list I chemicals. *Shani Distributors,* 68 FR 62324 (2003); *CHM Wholesale Co.*, 67 FR 9985 (2002); *See Aqui Enterprises, supra,* at 12578.

In the instant matter, it appears that the investigative process was, to some degree, compromised because of the inability of DEA personnel to verify the Respondent's sale of pseudoephedrine to various customers. The inability to verify these transactions may have been attributed to a number of factors, including, but not limited to, Respondent's poor record keeping, its distribution to customers that could not later account for the product, and/or distribution to customers that were not candid with DEA investigators about their business relationships with the Respondent or their receipt of listed chemicals.

Nevertheless, the Acting Deputy Administrator is deeply concerned with the circumstances surrounding the consistent denials by several of the Respondent's customers when questioned about their purchase of pseudoephedrine from the Respondent. The Acting Deputy Administrator finds it somewhat inconceivable, and beyond mere coincidence that several of these customers with apparent longtime business ties to the Respondent (having purportedly purchased large quantities of pseudoephedrine from the Respondent) would, in practically uniform fashion, become totally unfamiliar with such a significant business relationship. If, on the other hand these denials are to be believed, then further doubt is cast upon the Respondent's ability to responsibly handle listed chemicals because of the apparent inability to adequately track the distribution of these products. What is certain here, is the record is unclear as to the disposition of large quantities of pseudoephedrine products that were purportedly sold to business entities in Florida, New Jersey and Michigan.

For example, with respect to Ali's West Indian African and American located in the Tampa area, DEA personnel were informed in May 2001 that Ali's had discontinued business three years prior, and Third World Grocers had been operating at that location during that same period. The record in this proceeding indicates that the Respondent shipped bottles of pseudoephedrine to this establishment in 1999 and 2000. Further review of the Respondent's invoices does not reflect shipments of pseudoephedrine to Third World Grocers or anyone associated with this concern. It appears that these products were shipped to Ali's during a period when the store changed ownership. However, there is no evidence in the record regarding the disposition of large quantities of pseudoephedrine that were shipped to the former business address of Ali's.

The same circumstances were present with regard to the Respondent's sale of pseudoephedrine products to Superfood Super Market, another Tampa area customer. Invoices of the Respondent reveal the sale of pseudoephedrine to Superfood Super Market, however, the location where these products were delivered was occupied by a business concern by the name of Y &S Supermarket. When questioned by a DEA investigator, the owner of Y & S claimed to have never heard of the Respondent and that his store did not sell list I products. Of greater concern however, is the record in this matter does not shed any light on the disposition of large quantities of pseudoephedrine that were purportedly shipped to this location.

Similarly, with respect to the sale of pseudoephedrine to Cedar Market, the Respondent's records reveal that the customer purchased caseload quantities of pseudoephedrine from the Respondent in 1999 and 2000, but according to a DEA investigator the store's management had not heard of the Respondent. The Acting Deputy Administrator also finds curious, the Respondent's sale of forty-three cases of pseudoephedrine to Georgia Meat Market, an establishment that specialized in the sale of meat products, and the fact that the Respondent's invoices identified these transactions as having been made to a discount store.

With regard to Respondent's New Jersey customer, Getty Deli, the Acting Deputy Administrator finds disturbing, evidence in the record of the Respondent's apparent distribution of listed chemicals to this customer, which is totally at odds with the recollection of Getty's owner who in a written statement, denied ever purchasing or selling any products of the Respondent. In Michigan, and despite distribution records to the contrary, DEA investigators conducting verifications of Respondent's customers were told by the owners of Dollar City Plus, a dollar store, Duke's Oil, a Detroit-area gas station, and Harmon Mini Mart in Highland Park, that they had never dealt with the Respondent or only ordered from distributors in Michigan.

While not asserting any wrongdoing on the part of any of the above-referenced business establishments, the Acting Deputy Administrator remains concerned about the circumstances surrounding DEA's unsuccessful attempts at conducting customer verifications. The consistent, across-the-board denials by these firms of any business ties to the Respondent left DEA personnel in an untenable situation and rendered them unable to establish the validity of the distributions of a highly abused product. Consequently, DEA's inability to corroborate the Respondent's records of regulated transactions raise questions not only to the accuracy of the Respondent's distribution records and the legitimacy of its customer base, but most significant, raise further questions about the ultimate disposition of the listed chemical products purportedly distributed to those customers. Therefore, with respect to the eight customers referenced above, the Acting Deputy Administrator finds that DEA's inability to verify the distribution of list I chemicals to these establishments is relevant under factor five.

As noted above, the Government filed exceptions to the Opinion and Recommended Ruling of Judge Bittner. The Acting Deputy Administrator has addressed in this final order each of the matters raised in the Government's exceptions, specifically, arguments raised with respect to the interlocutory appeal, the results of the DEA accountability audit of Respondent's handling of pseudoephedrine products, and evidence of DEA site visits to purported customers of the Respondent. Therefore, those matters will not be revisited here.

On December 23, 2002, the Respondent also filed exceptions to Judge Bittner's recommended ruling. In its exceptions, the Respondent argued in relevant part, that ''its post-hearing submission * * * fully and completely provides a basis for the conclusions that [Respondent's] continued registration is not inconsistent with the public interest.'' While not addressing any specific matter raised by the Opinion and Recommended Ruling of the Administrative Law Judge, the Respondent asserts generally that the evidence in this proceeding does not support the revocation of its DEA Certificate of Registration. By not providing counter-arguments to any specific factual finding, legal conclusion or recommendation of the Administrative Law Judge, the Acting Deputy Administrator is limited in giving any consideration to the Respondent's generally stated exceptions. As a result, the Respondent's exceptions to the Opinion and Recommended Ruling are not sufficient to impact the ruling in this matter.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, 002330BNY, previously issued to Branex, Incorporated, be, and it hereby is, revoked. the Acting Deputy Administrator further orders that any pending applications for renewal or modification of said registration be, and they hereby are, denied. This order is effective March 26, 2004.

Dated: February 10, 2004.

**Michele M. Leonhart,**

*Acting Deputy Administrator.*

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**BILLING CODE 4410–09–M**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Manufacturer of Controlled Substances; Notice of Registration

By Notice dated January 27, 2003, and published in the **Federal Register** on February 6, 2003 (68 FR 6183), Houba, Inc., 16235 State Road 17, Culver, Indiana 46511, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of two basic classes of Schedule II controlled substances, oxycodone (9143) and hydrocodone (9193).

Two registered manufacturers of bulk controlled substances filed comments and objections in response to the Notice in a timely manner. Both objectors filed comments and objections with respect to oxycodone and hydrocodone. By Notice dated May 23, 2003 and published in the **Federal Register** on June 11, 2003 (68 FR 35006), the DEA acknowledge the receipt of the comments and objections, and its intent to investigate and resolve the issues raised.

Both objectors argue that Houba, Inc. (hereafter referred to as Houba) cannot prove its registration as a bulk manufacturer of opiates is in the public interest, that Houba is in a precarious financial state which could have a negative impact on its ability to fulfill its activity as a bulk manufacturers, that Houba does not have adequate experience as a manufacturer, that Houba will not promote technical advances, that Houba's registration is not required to produce an adequate and uninterrupted supply of oxycodone and hydrocodone, that there is sufficient competition with the present bulk manufacturers, and that Houba's registration will add to the risk of diversion both domestically and internationally. Additionally, the first objector argues that Houba's parent company can control Houba's management and operations and the parent company has a history of non-compliance with Federal laws and regulations. Both objectors request that DEA issue an Order to Show Cause, pursuant to 21 CFR 1301.37(a) by one objector and pursuant to 21 CFR 1301.44(a) and 1301.48(a) by the other objector, as to why the agency should not deny Houba's application for re-registration on the ground that Houba has not demonstrated that its application is in the public interest. (Title 21 CFR 1301.48 was deleted and currently is re-codified under 21 CFR 1301.37 in 1997.)