directed the Office of Management and Budget (OMB) to issue government-wide guidelines that ''provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by Federal agencies.'' Within one year after OMB issues its guidelines, agencies must issue their own guidelines that will describe internal mechanisms by which agencies will ensure that their information meets the standards of quality, objectivity, utility and integrity. The mechanism also must allow affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines.

OMB issued its final guidelines on September 28, 2001 (66 FR 49718), but requested additional comment on one component of the OMB guidelines. The OMB guidelines addressing additional public comment were published on January 3, 2002 (67 FR 369), and republished on February 22, 2002 (67 FR 6452). In accordance with the statute, agencies must issue their final guidelines by October 1, 2002. The agencies' draft guidelines need not be published in the **Federal Register**, but agencies should provide notification in the **Federal Register** that the draft guidelines are available on agencies' websites.

HUD announced the availability of its draft guidelines for review on HUD's website by **Federal Register** notice published on May 30, 2002 (67 FR 37851). The May 30, 2002, notice solicited public comments through July 1, 2002.

This notice published in today's **Federal Register** advises the public that HUD is extending the public comment period to July 17, 2002.

Dated: June 10, 2002.

Vickers B. Meadows,

Assistant Secretary for Administration.

[FR Doc. 02–15119 Filed 6–14–02; 8:45 am]

BILLING CODE 4210–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–310–1820–AE]

Notice of Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior, Northwest California Resource Advisory Council, Ukiah, California.

ACTION: Notice of Meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committees Act (Public Law 92–463) and the Federal Land Policy and Management Act (Public Law 94–579), the U.S. Bureau of Land Management's Northwest California Resource Advisory Council will meet Wednesday and Thursday, July 17 and 18, 2002, for a field tour and business meeting.

SUPPLEMENTARY INFORMATION: The meeting begins at 10 a.m. Wednesday, July 17, at the Yolo County Regional Park, 10 miles north of Rumsey, on California Highway 16. The members will depart immediately for a field tour and raft trip through parts of the BLM Cache Creek Natural Area. On Thursday, July 18, the business meeting begins at 8 a.m. in the Conference Room of the Ukiah Field Office, 2550 North State St., Ukiah. Agenda items include an update on Headwaters Forest Reserve Planning, review of the draft management plan and Environmental Impact Statement for the Cache Creek Natural Area, a status report on the BLM's vegetation management EIS, and a status report on planning for the South Spit. Time will be set aside for public comments.

Depending on the number of persons wishing to speak, a time limit may be established.

FOR ADDITIONAL INFORMATION: Contact Lynda J. Roush, BLM Arcata Field Manager, at (707) 825–2300, or Public Affairs Officer Joseph J. Fontana at (530) 252–5332.

Joseph J. Fontana,

Public Affairs Officer.

[FR Doc. 02–15203 Filed 6–14–02; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–350–1820–AE]

Notice of Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior, Northeast California Resource Advisory Council, Cedarville, California.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committees Act (Public Law 92–463) and the Federal Land Policy and Management Act (Public Law 94–579), the U.S. Bureau of Land Management's Northeast California Resource Advisory Council will meet Thursday and Friday, July 11 and 12, 2002, at the BLM Surprise Field Office, 602 Cressler St., Cedarville, California.

SUPPLEMENTARY INFORMATION: The meeting begins Thursday, July 11, at 9 a.m. at the Surprise Field Office. Members will convene, then depart for a field tour in the Homecamp area. On Friday, July 12, the business meeting begins at 8 a.m. in the Conference Room of the Surprise Field Office. Agenda items include sage grouse conservation planning, the Homecamp land acquisition proposal, land use planning for the Black Rock Desert-High Rock Canyon-Emigrant Trails National Conservation Area, and development of a juniper management strategy. Time will be set aside at 1 p.m. for public comments. Depending on the number of persons wishing to address the council, a time limit could be established.

FOR FURTHER INFORMATION: Contact BLM Alturas Field Manager Tim Burke at (530) 257–4666, or Public Affairs Officer Joseph J. Fontana, (530) 252–5332.

Joseph J. Fontana,

Public Affairs Officer.

[FR Doc. 02–15204 Filed 6–14–02; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 00–41]

Mediplas Innovations; Suspension of Shipments

By Orders dated August 14, 2000, the Administrator of the Drug Enforcement Administration (DEA) suspended two shipments, one for 518.5 kilograms of ephedrine, and another for 798.55 kilograms of pseudoephedrine, from Getz Pharma, Karachi, Pakistan, to Mediplas Innovations, Inc. of San Antonio, Texas. According to the two Orders To Suspend Shipment (OTSS), the suspension was based on the facts that: (1) Mediplas was disqualified as a regular importer pursuant to 21 U.S.C. 971(b)(2) on December 22, 1999, requiring it to provide the DEA with a 15-day advance notification for each import of listed chemicals; (2) Mediplas failed to timely notify DEA of these shipments, in violation of 21 CFR 1313.31 (2000); (3) Mediplas's pseudoephedrine products have been found at clandestine laboratories, and at laboratory dumpsites; and (4) Mediplas's only customer for this product, Wholesale Outlet, is the current subject of an active DEA investigation as a possible source of diversion.

By letter dated September 8, 2000, Mediplas Innovations, Inc. requested a hearing in this matter. A hearing was held before Administrative Law Judge Gail A. Randall in Arlington, Virginia, on December 20–21, 2000, and on January 31 and February 1, 2001, in Houston, Texas. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed Proposed Findings of Fact, Conclusions of Law, and Argument. On October 4, 2001, Judge Randall issued her Recommended Rulings, Findings of Fact, Conclusion of Law, and Decision, recommending that the Administrator find DEA was not justified in issuing the OTSS and that said OTSS should be terminated and the chemicals released to Mediplas. On October 24, 2001, the Government filed Exceptions to the Administrative Law Judge's Opinion and Recommended Ruling (Exceptions). Thereafter, on November 20, 2001, Judge Randall transmitted the record of these proceedings to the Deputy Administrator for final decision.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts in full the Findings of Fact of the Administrative Law Judge, and rejects the Conclusions of Law, except as hereinafter set forth. Furthermore, the Deputy Administrator rejects the recommendation of the Administrative Law Judge.

Mr. Laeeq Ahmed is the proprietor of Mediplas Innovations, Inc. (Mediplas). After a military career in the Pakistani Air Force, Mr. Ahmed worked for two years as a consulting project manager in Pakistan. In 1991, he came to the United States. Initially, he worked for his brother in restaurant management in Texas. After approximately one and one-half years, he established his own retail store, a convenience store. While operating this convenience store, he began importing novelty items. He also sold groceries, novelties, office supplies, and over-the-counter medicines, to include an ephedrine product, ''Mini Thins,'' in 60 count bottles. He only purchased Mini Thins from a wholesaler in small quantities, however, usually one to two dozen bottles at a time.

Mr. Ahmed has been an importer for approximately four or five years. He wanted to enter the pharmaceutical manufacturing market. After investigating the manufacturing process in Pakistan from Getz Pharmaceutical. Prior to arranging the exportation of ephedrine or pseudoephedrine from Pakistan, Mr. Ahmed obtained approval from the Health Ministry, the Narcotics Division, the Customs Division, and the Ministry of Exports in Pakistan. He also received approval from the World Health Organization.

Mr. Ahmed worked closely with the San Antonio office of the DEA as he created his new business. On December 12, 1998, Mediplas submitted an application to the DEA for registration as an importer of ephedrine. In March of 1999, the DEA conducted a pre-registration investigation, inspecting Mediplas's proposed registered location, and providing Mr. Ahmed with copies of the applicable provisions from the Code of Federal Regulations. Mr. Ahmed was reminded by DEA personnel to report suspicious orders of listed chemicals to the DEA. Mr. Ahmed was also provided information regarding the illicit use of List I chemicals as precursor chemicals in the illicit manufacture of methamphetamine. Specifically, Mr. Ahmed was provided a ''Red Warning Notice'' that advised him about the seizure at clandestine methamphetamine laboratories of combination ephedrine and pseudoephedrine products. The DEA subsequently identified the parent company of Getz Pharma, identified its corporate officers, located its web site, and located its Pakistan, U.S., and other overseas offices. On August 4, 1999, representatives from the DEA again visited Mediplas's location to obtain additional information. Mr. Ahmed fully cooperated with the representatives.

Judge Randall found Mr. Ahmed credibly concurred in his testimony that, prior to registered with the DEA, Mediplas had received information about the importer registration process, the DEA rules, regulations, and procedures pertaining to the importation and handling of ephedrine and pseudoephedrine, and the procedures DEA used to communicate with licensed importers. Also as part of the pre-registration inspection of Mediplas, the DEA conducted criminal record checks and state and local agency checks, with negative results.

Mr. Ahmed informed the DEA that Mediplas's entire business was handling List I chemicals. Mediplas intended to import finished tablets packaged in sealed bottles, shrink wrapped, boxed, and in cartons.

Mr. Ahmed also agreed to provide the DEA with a list of prospective customers, and to keep this list accurate. Mr. Ahmed agreed not to distribute any Mediplas products to entities not registered with the DEA to handle listed chemicals. The record contains no evidence that Mr. Ahmed has failed to adhere to his agreement.

On April 29, 1999, the DEA issued Mediplas DEA Certificate of Registration number 004230MNX, that granted Mediplas authorization to import ephedrine. Mediplas also obtained a permit from the State of Texas to handle precursor chemicals.

Mediplas imported its first ephedrine products after April of 1999. Initially, Mediplas's ephedrine product was labeled ''Mini Twin,'' but this name was later changed to ''Min Twin.'' Mr. Ahmed credibly testified that he had seen Mediplas products on display at convenience stores and gas stations located in Houston, Texas and between Houston and San Antonio, Texas.

On October 25, 1999, Mr. Ahmed submitted a letter to the DEA, indicating his desire to add pseudoephedrine to his DEA registration. Mr. Ahmed requested DEA provide guidance on the procedures he should follow to add pseudoephedrine to his registration. Subsequently, in the early part of 2000, Mr. Ahmed also spoke to a DEA representative at the DEA Headquarters about modifying the Certificate of Registration so that Mediplas could import pseudoephedrine. By letter dated January 4, 2000, Mr. Ahmed informed a DEA Diversion Investigator (DI) that Mediplas's application for registration to handle pseudoephedrine had been approved by the FDA.

Mediplas named its pseudoephedrine product Twin Pseudo. Mediplas imported Twin Pseudo in 120 count bottles. Mediplas did not distributed this product to retail outlets; it only sold this product to its sole distributor, Wholesale Outlet, On April 10, 2000, DEA Report of Investigation was prepared noting that Mediplas's registration was modified to authorize it to import pseudoephedrine. By letter dated February 15, 2000, however Mr. Ahmed informed the DI of the arrival of an importation of pseudoephedrine and the subsequent sale of that shipment to Wholesale Outlet. Mr. Ahmed enclosed a copy of the sales of that shipment to Wholesale Outlet. Mr. Ahmed enclosed a copy of the sales report concerning this shipment.

Further, from DEA reports of investigation, and based on Mediplas invoices dated between November 1999, to April 6, 2000, the DEA reported that, (1) on January 13, 2000, Mediplas purchased its first shipment of Twin Pseudo, and the report noted the 11 batch numbers and quantities purchased; (2) on January 25, 2000, Mediplas purchased its second shipment of Twin Pseudo, and the

report noted the quantities and the 7 batch numbers of the product purchased; (3) on February 7, 2000, Mediplas sold its first shipment of Twin Pseudo to Wholesale Outlet; (4) on March 1, 2000, Mediplas sold its second shipment of Twin Pseudo to Wholesale Outlet. On April 6, 2000, the DEA served an administrative subpoena upon Mediplas. DEA representatives reviewed receiving and distribution records, and conducted an on-site inspection. An inventory was also conducted and an accountability audit was performed. Mr. Ahmed was advised that there were no discrepancies found during this investigation.

Pseudoephedrine is a List I chemical pursuant to 21 CFR 1310.02(a)(11). A transaction involving more than one kilogram of pseudoephedrine in a month requires a fifteen day advance notification to the DEA. Pseudoephedrine is a legitimately imported and distributed product used in the manufacture of nasal decongestants. Pseudoephedrine is also a precursor chemical used in the illicit manufacture of methamphetamine.

Ephedrine is a List I chemical pursuant to 21 CFR 1310.02(a)(3). Any entity importing any quantity of ephedrine must notify the DEA fifteen days in advance of the importation. Ephedrine is a legitimately imported and distributed product used in the production of bronchial dilators and asthma relief medication. Ephedrine is also a precursor chemical used in the illicit manufacture of methamphetamine.

Methamphetamine is a Schedule II controlled substance having approved uses when taken under a physician's supervision as an FDA-approved treatment for attention deficit disorder with hyperactivity, as a treatment for obesity as a short term adjunct in a regimen of weight reduction, and as a treatment for narcolepsy. Methamphetamine also has a high abuse potential, however, being ranked among the top five controlled substances for abuse. Illicit methamphetamine is often manufactured in clandestine laboratories, often organized by crime groups. The record shows the majority of illicit methamphetamine laboratories currently utilize tablets of ephedrine and pseudoephedrine in the production process. These substances are interchangeable with respect to the manufacture of methamphetamine.

Prior to importing ephedrine and over-the-threshold amounts of pseudoephedrine products, each importer is required to provide the DEA with notice 15 days prior to the importation of the product into the U.S. The purpose of the 15-day notice is to allow the DEA time to evaluate the proposed import and to determine whether there exits grounds to believe that the proposed import may be diverted.

To accomplish this notification the importer must use the DEA Form 486 (Form 486). The DEA considers notification has occurred when the agency physically receives the Form 486, as indicated by the agency date stamp on the form. The importer may submit the form by mail or by electronic facsimile, and approximately 99 percent of Form 486s are received by the DEA via facsimile. In the event that the actual date of the import does not match the date projected on the Form 486, the importer is requested to file an amended Form 486, showing the actual date of importation. Mediplas has filed such amended Form 486s.

When an importer fails to file the Form 486 in a timely manner, a record is created and maintained by DEA. If these violations become repetitive, then the local DEA office is notified, so that representatives from the local office can address these violations with the registrant.

On December 22, 1999, the DEA sent a notice to Mediplas, informing Mediplas that it was required to provide 15-day advanced notice prior to the importation of ephedrine, regardless of quantity, and pseudophedrine, for all imports exceeding one kilogram.

The record contains fourteen Form 486s filed by Mediplas between January and June of 2000. Six of these forms were filed in compliance with the 15-day rule. Eight were not filed in compliance with the rule. Judge Randall found Mr. Ahmed credibly testified that he had retained a customs house broker, whom he had authorized to file the Form 486s with DEA. The broker both faxed and mailed the forms to the DEA. Mr. Ahmed credibly testified that he first learned that the DEA had not timely received the faxed Form 486s from Mediplas's customs broker at this suspension hearing. For the shipment of 518.5 kilograms of ephedrine, the Form 486 was received by the DEA on June 5, 2000, noting that the shipment was due to arrive in the U.S. on June 16, 2000. For the shipment of 798.55 kilograms of pseudophedrine, the Form 486 was received by the DEA on June 5, 2000, noting that the shipment was due to arrive in the U.S. on June 16, 2000. For the shipment of 798.55 kilograms of pseudophedrine, the Form 486 was received by the DEA on June 5, 2000, noting that the shipment was due to arrive in the U.S. on June 16, 2000. Thus, the forms were not timely filed, because both forms were received by the DEA 11 days in advance of the projected import date, rather than the required 15 days.

The record contains no evidence that the DEA, prior to the OTSS, had rejected or returned to Mediplas for errors, any of Mediplas's Form 486s, or had notified Mediplas of any untimely filings.

Wholesale Outlet is located in Beaumont, Texas. At the time of the hearing, Wholesale Outlet held DEA Certificate of Registration, 001664WEY, valid until May 31, 2001, as a distributor of the List I chemicals pseudoephedrine, ephedrine, and phenylpropanolamine. Mr. Ahmed decided to distribute Mediplas ephedrine products to a single distributor, Wholesale Outlet. In October of 1999, Mediplas and Wholesale Outlet entered into a ''Distribution Contract,'' (Contract) giving Wholesale Outlet the exclusive rights to buy and sell Mediplas product brands. As of the date of the OTSS, the Contract was still in effect between Mediplas and Wholesale Outlet. In November of 1999, Mediplas and Wholesale Outlet agreed that Mediplas would also see Wholesale Outlet pseudoephedrine products. Originally, the order was 500 cases of pseudoephedrine products a month.

In October of 1999, Mediplas sold Wholesale Outlet 432 bottles of ephedrine 12.5 mg, totaling 25,290 tablets at a total price of $527.04. In November of 1999, Mediplas sold Wholesale Outlet 72,000 bottles of ephedrine 12.5 mg, totaling 4,320,000 tablets at a total price of $90,000. In December of 1999, Mediplas sold Wholesale Outlet 5,760 bottles of ephedrine 12.5 mg, totaling 345,600 tablets at a price of $7,200, and 36,000 bottles of ephedrine 25 mg, totaling 2,160,000 tablets at a price of $45,000. In January of 2000, Mediplas sold Wholesale Outlet 21,600 bottles of ephedrine 12.5 mg, totaling 1,296,000 tablets at a price of $27,000, and 7,200 bottles of ephedrine 25 mg, totaling 432,000 tablets at a price of $9,000. In February of 2000, Mediplas sold Wholesale Outlet 43,200 bottles of ephedrine 12.5 mg, totaling 2,592,000 tablets at a price of $54,000, and 72,022 bottles of pseudophedrine 60 mg, totaling 8,642,640 tablets at a price of $185,040. Finally, in March of 2000, Mediplas sold Wholesale Outlet 36,000 bottles of ephedrine 12.5 mg, totaling 2,160,000 tablets at a price of $45,000, and 63,072 bottles of pseudophedrine 60 mg, totaling 7,568,640 tablets at a price of $162,095.04. Judge Randall found no evidence that the lot numbers represented by these sales, or that any

of this product from these batch numbers, had been seized at illicit laboratories or dump sites.

In a review of Mediplas's sales figures for a three-week period from February 7, 2000, to March 1, 2000, a DEA DI with experience in listed chemical investigations testified that the found such total sales ''suspicious,'' and the highest totals he had ever seen for a three-week period. Specifically, the DI noted that Mediplas had sold 16,211,280 pseudoephedrine tablets between February 7, 2000, and March 1, 2000. He noted that, for the entire year of 1997, Warner Lambert, a national distributor of such products, sold 38,287,089 tablets of product containing pseudoephedrine. The DI noted that Mediplas's sales in an approximately three-week time period in the year 2000, represented 42 percent of the amount of pseudoephedrine product Warner Lambert distributed for the entire calendar year of 1997.

The DI also testified that he found Mediplas's packaging of pseudoephedrine 60 mg single-entity product suspicious, because he had never seen a 120-count bottle in any retail business establishment. Mr. Ahmed agreed that he had not seen such bottles of 120-count pseudophedrine tablets in a store. The Deputy Administrator concurs with Judge Randall's finding that the record contains no evidence that any DEA personnel communicated these specific packaging concerns to any representatives of Mediplas prior to this hearing, however.

In May of 2000, DEA asked Mr. Ahmed to provide a customer list for Wholesale Outlet. Mr. Ahmed complied with the DEA's request. The list consists of fifteen pages. Specifically, for the ephedrine product, ''Mintwin,'' Wholesale Outlet lists 119 customers from Texas, Louisiana, Michigan, Minnesota, and California. For the ephedrine product, ''Twincare,'' Wholesale Outlet lists 8 customers, all in Texas. For the ephedrine product, ''Minitwin,'' Wholesale Outlet lists 20 customers from Louisiana, Georgia, Michigan, Colorado, Texas, Florida, and Washington.

For the pseudoephedrine product, ''Twin-Pseudo,'' Wholesale Outlet lists 53 customers from Utah, Washington, Arkansas, Missouri, Nevada, Oregon, Michigan, Colorado, Texas, Arizona, Montana, Ohio, Oklahoma, and Florida. Wholesale Outlet's customer list is a mixture of wholesale and retail establishments, including convenience stores, gasoline stations, supermarkets, and wholesale grocers and distributors.

On August 3, 2000, the DEA obtained a criminal search warrant for Wholesale Outlet. During the execution of this warrant, DEA representatives obtained information for Wholesale Outlet's receiving records indicating that, aside from Mediplas, Wholesale Outlet purchased List I chemicals from at least six additional suppliers. This warrant was the result of an ongoing DEA investigation into Wholesale Outlet's listed chemical handling practices, as testified to by a number of Government witnesses.

The DEA has implemented a Warning Letter program in response to input provided by the chemical industry. The DEA Warning Letter program is designed to notify manufacturers, distributors, and other handlers of List I Chemicals of the diversion of their products to methamphetamine laboratories or dump sites. Each Warning Letter provides approximately the same information: the date and location of the discovery, the name of the product discovered, the quantity of product discovered, and the lot numbers of the product discovered, if available. In addition, each Warning Letter is accompanied by an attachment setting forth applicable statutes and regulations concerning various aspects of handling listed chemicals. At least nine Warning Letters were delivered by representatives from the DEA's San Antonio office to Mr. Ahmed between approximately June through October, 2000, regarding seizures of the company's imported listed chemical products found ''involved in activities related to the illegal manufacturing process of methamphetamine.'' The nine Warning Letters document the diversion of over eleven thousand bottles of Mediplas's List I chemicals products to the illicit manufacture of controlled substances. In addition, four Warning Letters were delivered to Wholesale Outlet, documenting the diversion of additional List I chemical products.

By letters dated June 13, 2000, and July 10, 2000, Mr. Ahmed informed Wholesale Outlet of the products found in clandestine laboratories as listed in the Warning Letters. In each letter, Mr. Ahmed also requested that Wholesale Outlet ''stop sale to the above locations immediately.'' Wholesale Outlet responded at least once, stating that it would stop selling to those locations.

By letters dated November 11, 1999, December 7, 1999, February 15, 2000, March 15, 2000, March 28, 2000, April 28, 2000, and June 5, 2000, Mr. Ahmed informed the DEA of shipments of listed chemicals, both ephedrine and pseudoephedrine, he had received and subsequently sold to Wholesale Outlet, and of the samples he had provided the DEA, as requested. He noted that he had no shortages and no remaining stock of listed chemicals.

Pursuant to 21 U.S.C. 971(c)(1), and delegations of authority thereunder at 28 CFR 0.100(b) and 0.104, the Deputy Administrator ''may order the suspension of any importation * * * of a listed chemical * * * on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance.'' To suspend a shipment pursuant to 21 U.S.C. 971(c)(1), the DEA must provide written notice to the regulated person, and include the legal and factual basis for the suspension order.

According to 21 U.S.C. 971(a) and 21 CFR 1313.12(a), each ''regulated person'' who imports or exports a threshold quantity of a listed chemical must notify the Attorney General ''not later than 15 days before the transaction is to take place.'' A ''regulated person'' is ''any * * * corporation * * * who manufactures, distributes, imports, or exports a listed chemical[.]'' 21 CFR 1300.02(b)(27); *see also* 21 U.S.C. 802(38). A ''chemical importer'' is a ''regulated person'' responsible ''for determining and controlling the bringing in or introduction of the listed chemical into the United States.'' *See* 21 CFR 1300.02(b)(8).

Further, pursuant to 21 U.S.C. 830(b)(1)(A) and 21 CFR 1310.05(a)(1), a regulated person is required to report to the DEA ''[a]ny regulated transaction involving an extraordinary quantity of a listed chemical * * * or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.''

The regulations also provide that ''the Agency shall have the burden of proving that the requirements * * * for such suspension are satisfied.'' 21 CFR 1313.55. The regulations state that the purpose of a hearing regarding suspended shipments is for ''receiving factual evidence regarding the issues involved in the suspension.'' 21 CFR 1313.52. Thus, the Government must prove by a preponderance of the evidence that grounds exist to conclude that ''the chemical may be diverted to the clandestine manufacture of a controlled substance.'' 21 U.S.C. 971(c)(1); *see also* 21 CFR 1313.41(a) (2000); *Suspension of Shipment Cases January 17, 1998 Shipment of 10,000 Kilograms of Potassium Permanganate, December 16, 1997 Shipment of 20,000 Kilograms of Potassium Permanganate and November 17, 1997 Shipment of 20,000 Kilograms of Potassium*

Permanganate [hereinafter *Suspension of Shipment Cases*], 65 FR 51,333, 51,336–337 (2000). The test is whether or not the listed chemicals *may* be diverted, not whether the listed chemicals actually will be diverted.

The applicable statutory provisions and legislative history are silent concerning what constitutes ''grounds'' for the Government to believe a listed chemical may be diverted to clandestine manufacturing. Likewise, the statute and the regulations are also silent as to the factors to be considered to determine if ''grounds'' exist to conclude that the shipment ''may be diverted.''

To date, past Deputy Administrators have decided three cases concerning this issue. *Suspension of Shipment Cases,* 65 FR 51,333 (2000); *Yi Heng Enters. Dev. Co.,* [hereinafter *Yi Heng*] 64 FR 2,234 (1999); *Neil Laboratories, Inc.,* 64 FR 30,063 (1999). In each case, the then-Deputy Administrator concluded that ''ample'' and ''substantial'' evidence existed to suspend the shipments at issue. In so concluding, Judge Randall found past Deputy Administrators evaluated the following six factors in determining whether a shipment may be diverted: (1) The status of the shipper to ensure the requesting party is entitled to the hearing, (2) the regulated person's compliance history as a handler of listed chemicals, to include whether the advance notification regulations had been fulfilled, (3) the regulated person's sales practices, including the legitimacy of the names and addresses of each proposed recipient of the shipment, (4) the quantities of chemical sold by the regulated person to its immediate customers, (5) the legitimacy of the proposed importation through consultation with the regulated person's government to ensure the regulated person was authorized to receive the proposed shipment, and (6) any relevant law enforcement records concerning the regulated person.

The Deputy Administrator concurs with Judge Randall's finding that these were factors considered in the previous suspension order cases. The Deputy Administrator finds, however, that these factors are only illustrative of the types of evidence relevant to justifying a suspension order, and the enumeration of these factors herein does not exhaust the range of evidence or factors that can be used to justify a suspension order pursuant to 21 U.S.C. 971(c)(1). The Deputy Administrator finds that a totality of the circumstances test is appropriate in determining whether a suspension order is justified.

The DEA provided notice for these suspended shipments by way of the Orders to Suspend Shipment. The Orders outlines several grounds for the DEA's belief that the two shipments, one of ephedrine, and one of pseudoephedrine, would be diverted to the clandestine manufacture of controlled substances. Thus, the 21 U.S.C. 971(c)(1) notice requirement has been met.

A second preliminary determination is whether the requesting party is entitled to a hearing, 21 U.S.C. 971(c)(2) and 21 CFR 1313.52. The DEA previously has held that a principal party in interest of a shipment of a listed chemical would be the ''importer'' for purposes of 21 U.S.C. 971. Essentially, ''if the title to the [listed chemical] passed to [the regulated person] before the chemical entered the United States, then the regulated person] is the principal party in interest.'' *Suspension of Shipment Cases,* 65 FR at 51,336; *Yi Heng,* 64 FR at 2,235.

In this proceeding, there was no dispute that as the DEA-registered importer with title to the chemicals, Mediplas was the principal party in interest in the suspended chemicals. Thus, the Deputy Administrator concurs with Judge Randall's conclusion that Mediplas is considered the regulated person for the purposes of 21 U.S.C. 971, and is entitled to this hearing.

As a further preliminary matter, a past Administrator previously has ruled that the purpose of a hearing regarding the suspension of a chemical shipment ''is to determine whether DEA had evidence at the time to support its finding that the chemical may be diverted, thereby warranting the suspension of the shipment.'' *Suspension of Shipment Cases,* 65 FR at 51,337. In addressing the scope of the hearing, however, the then-Administrator found relevant evidence justifying an order to suspend a chemical shipment must be limited to ''the evidence available to DEA at the time of the suspensions and to the evidence presented by [the regulated person] of its business practices prior to the suspensions and its reputation as a law-abiding company.'' *Id.*

Likewise, in the present case, both the Government and Mediplas were limited to evidence acquired or generated prior to the date of the OTSS. At the hearing in this matter, both the Government and counsel for Mediplas sought to introduce into evidence various exhibits that were either discovered or generated subsequent to the date of the OTSS. Judge Randall adhered to the *Suspension of Shipment Cases,* evidentiary ruling, and did not accept into evidence any proposed exhibit discovered or generated subsequent to the date of the OTSS, as being beyond the scope of the hearing. Pursuant to the requests of the parties, however, Judge Randall appended the rejected exhibits to the record for consideration by the Deputy Administrator, should he choose to reconsider the evidentiary ruling. Subsequently, the Government in its Exceptions specifically requested such reconsideration. For the reasons stated below, the Deputy Administrator hereby reconsiders the evidentiary ruling rendered in the *Suspension of Shipment Cases,* and finds instead that relevant evidence is not limited to that discovered or generated prior to the date of issuance of the suspension order.

In finding that the purpose and scope of the 21 U.S.C. 971(c)(2) hearing is to determine whether DEA had evidence at the time of the issuance of the suspension order to support its finding that the chemicals may be diverted, the then-Administrator compared the suspension of shipment hearing provisions with those regarding revocation of DEA registrations pursuant to 21 U.S.C. 824. The then-Administrator found that since there was no provision in 21 U.S.C. 971 for the institution of proceedings to determine disposition of the suspended chemicals, it was reasonable to conclude the focus of the hearing was whether the suspension order was justified. Since the then-Administrator found the focus of the hearing was justification of the suspension order, he limited his review to the evidence available to the DEA at the time of issuance of the suspension order.

The Deputy Administrator disagrees, and concludes as follows. 21 U.S.C. 971(c)(2) states in relevant part that ''[u]pon written request to the [DEA], a regulated person to whom an [suspension] order applies is entitled to an agency hearing on the record[.]'' Such hearings, as set forth at 21 CFR 1313.52, are ''for the purpose of receiving factual evidence regarding the issues involved in the suspension of shipments[.]'' The Deputy Administrator finds the cited language does not serve to limit his review to any given stage in the proceedings. To the contrary, the plain language of 21 CFR 1313.52 permits review of ''factual evidence regarding issues involved in the suspension[.]'' The Deputy Administrator finds the public interest, as well as the interests of both the DEA and regulated persons, are best served by consideration of evidence regarding the most current issues involved in the suspension, not just those frozen at the time of the issuance of the suspension order. The Deputy Administrator thus

finds the purpose of the 21 U.S.C. 971(c)(2) hearing is to address issues involved in the suspension as they stand at the time of the hearing. Therefore, factual evidence in the instant case regarding the issues involved in the suspension should not be limited only to that generated or discovered up to the time of issuance of the OTSS.

Moreover, contrary to the *Suspension of Shipments Cases* ruling at issue, the Deputy Administrator finds 21 U.S.C. 971(c)(1) adequately addresses the disposition of the suspended shipments. In relevant part, that provision states ''[f]rom and after the time when the [DEA] provides written notice of the [suspension] order to the regulated person, the regulated person may not carry out the transaction.'' The Deputy Administrator finds the intent of 21 U.S.C. 971(c) is not to permanently deprive the regulated person of the suspended chemicals. Indeed, the very use of the word ''suspensions'' in that subsection indicates the intent for a temporary detention. This conclusion is strengthened by the lack of any language in 21 U.S.C. 971 concerning the availability of forfeiture proceedings allowing DEA to permanently dispose of the suspended chemicals. Forfeiture of List I chemicals is addressed at 21 U.S.C. 824(f), and can only take place in conjunction with proceedings to suspend or revoke a DEA registration. Forfeiture of other listed chemicals suspended pursuant to 21 U.S.C. 971 is available pursuant to 21 U.S.C. 881(a). The record indicates that as of the time of the hearing, Mediplas's DEA registration was neither suspended nor revoked.

Therefore, if the suspension order is found to be justified, pursuant to the language of 21 U.S.C. 971(c)(1), ''the regulated person may not carry out *the transaction*.'' (Emphasis added). The focus of this language is upon the specific transaction underlying the suspension order. The Deputy Administrator finds this language permits the regulated person to carry out other transactions regarding the suspended chemicals, however, provided the regulated person complies with the requirements of 21 U.S.C. 971(a) by filing a substitute Form 486, providing DEA 15 days notice of a proposed alternative transaction. If the DEA objects to the proposed alternative transaction, then the process can start over, and a new suspension order issued. If the suspension order is found not to be justified at the time of the hearing, however, then the suspended chemicals can immediately be released to the regulated person and the original transaction allowed to take place. The Deputy Administrator therefore finds disposition of the suspended chemical shipments is adequately addressed, and thus that the ultimate purpose and scope of the 21 U.S.C. 971(c)(2) hearing is to determine whether the OTSS is justified at the time of the hearing.

As a result of his reconsideration of the *Suspension of Shipment Cases* evidentiary ruling, the Deputy Administrator has considered the entire record, including the previously rejected but appended exhibits of both parties, in reaching the conclusions set forth herein.

Judge Randall concluded that the Government had failed to carry its burden of proof in this matter, upon findings that the violations set forth by the Government did not support a conclusion that the shipments ''may be diverted,'' and also considering Mediplas's ''extraordinary and voluntary efforts * * * to comply with DEA's regulations and guidance[.]'' The Deputy Administrator disagrees, and finds as follows.

In interpreting 21 U.S.C. 971(c)(1), the Deputy Administrator finds that the plain language of the statute focuses solely upon whether the chemical shipment ''may be diverted[.]'' The culpability of any regulated person to whom a suspension order applies appears to be irrelevant to this determination. The Deputy Administrator notes that the Controlled Substances Act (CSA) distinguishes between regulatory actions involving DEA applicants and registrants that require a finding of culpability, such as the denial of an application for or the revocation of a DEA Certificate of Registration, in contrast to the issuance of a suspension order to a regulated person involving a temporary, limited detention that may be imposed without a finding of fault. *Compare* 21 U.S.C. 823 and 824 *with* 21 U.S.C. 971(c)(1). Only upon a finding of culpability can a DEA registrant permanently be deprived of controlled substances or List I chemicals, or a regulated person permanently be deprived of listed chemicals. 21 U.S.C. 824(f) and 881(a). The Deputy Administrator finds that in using such broadly drawn language, Congress has invited the use of the widest possible range of relevant evidence in determining whether a shipment ''may be diverted[.]''

A broad interpretation of 21 U.S.C. 971(c)(1) is also supported by DEA precedent. The Deputy Administrator notes that, in one of the previously cited DEA suspension of shipment cases, the then-Deputy Administrator significantly relied upon evidence of misconduct in handling listed chemicals by the regulated person's customers in finding the suspension order justified. In *Yi Heng,* it was argued that evidence of the activities of the regulated person's customers was irrelevant to the administrative proceeding regarding suspended shipments of a listed chemical. Specifically, counsel for the regulated person argued in *Yi Heng* that the regulated person engaged in a legitimate business; that there was no evidence that the regulated person had knowledge of the improper conduct of its customers; that the regulated person could not be held responsible for the bad acts of its customers; and that the regulated person had no control over the chemical once it was sold to its customers. The then-Deputy Administrator rejected these arguments, and considered evidence regarding the activities of both the regulated person and its customers. Specifically, the then-Deputy Administrator found that ''[t]he prior conduct of [the regulated person's] customers regarding [the chemicals] is clearly relevant in determining whether the shipments may be diverted.'' 64 FR at 2,235–6.

Such an interpretation is further supported by the policy behind the enactment of the Controlled Substances Act: ''The Congress makes the following findings and declarations * * * (2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.'' 21 U.S.C. 801. ''Congress [in enacting the CSA] was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.'' *United States* v. *Moore,* 423 U.S. 122, 135 (1975) (*citations omitted*). This reasoning applies with equal force to the diversion of listed chemicals by DEA registrants and regulated persons. The interpretation of 21 U.S.C. 971(c)(1) set forth herein advances the purposes of the CSA by providing the DEA with the increased ability to thwart the threatened diversion of listed chemical importations and exportations by allowing consideration of the widest-possible range of relevant evidence. Moreover, the culpability of affected parties has been found irrelevant in criminal and civil actions involving the public health, safety, and welfare and carrying far more serious consequences

that the relatively brief and limited detention authorized by 21 U.S.C. 971. *Cf. United States* v. *Dotterweich,* 320 U.S. 277 (1943) (upholding the Constitutionality of strict criminal liability for ''public welfare offenses'' involving drugs); *United States* v. *Balint,* 258 U.S. 250 (1922) (same); *United States* v. *Green Drugs,* 905 F.2d 694, 697–8 (3d Cir. 1990) (applying strict civil liability to CSA recordkeeping violations and affirming assessment of monetary penalty). In determining whether the OTSS in this case were justified, the Deputy Administrator therefore rejects Judge Randall's factor-by-factor analysis for a much simpler test: whether the totality of the circumstances provides grounds to believe that the suspended chemical shipments may be diverted.

In the instant case, the record shows the following: the nine Warning Letters issued to Mediplas provided substantial evidence documenting the diversion of thousands of bottles of its previously imported List I chemical products to ''clandestine manufacture of a controlled substance.'' 21 U.S.C. 971(c)(1). In addition, the Government provided evidence showing that Wholesale Outlet (1) was under DEA investigation related to its handling of listed chemical products; (2) was the subject of an August 3, 2000, DEA criminal search warrant related to the handling of its listed chemical products; and (3) was the subject of a DEA audit, discussed *infra,* documenting numerous and enormous shortages and overages of *inter alia* Mediplas List I chemical products running into the millions of dosage units. The Deputy Administrator finds this evidence provides ample justification for sustaining the OTSS in this case.

While there was no evidence in the record that Wholesale Outlet had a record of criminal convictions, the Deputy Administrator finds that evidence in support of grounds to believe the suspended chemicals may be diverted is not restricted to conclusive legal judgments. The Deputy Administrator concurs with the finding in the *Suspension of Shipment Cases,* where the then-Deputy Administrator concluded that ''[e]vidence of a violation of law is not necessary to demonstrate that the suspensions were lawful.'' *Id.* at 51,337.

In addition to this evidence, the record shows Mediplas violated applicable law and regulations with regard to its late-filed 486 forms and premature importations and distributions of the List I chemical pseudoephedrine, as set forth below.

The responsibilities of a regulated person include the obligation to file an advance notification to the DEA of the import of a listed chemical that meets the threshold amounts triggering the notification requirement. 21 U.S.C. 971(a); 21 CFR 1313.12. Although the record shows Mediplas filed such notifications for every shipment imported, the record contains eight Form 486s that Mediplas did not timely file during 1999 and 2000. The DEA previously has held that ''failure to file [advanced notification] by itself, does not justify the suspension of the shipments.'' *Suspension of Shipment Cases,* 65 FR at 51,336. Thus, failure to notify in itself does not justify the suspension, but it may be a factor to be considered in the analysis of whether there is the potential for diversion. The record demonstrates that Mediplas failed to provide timely notification using the Form 486 procedure in eight instances during the time period of January through June 2000, prior to importing listed chemicals into the United States. The Form 486s for the two suspended shipments at issue were each filed approximately four days late.

Judge Randall found it significant that Mr. Ahmed was unaware of the untimely filing of the forms. He had hired a customs house broker to prepare and submit this paperwork, and the broker had assured Mr. Ahmed that the forms were faxed and mailed to the DEA. Since Mr. Ahmed had not heard from the DEA concerning these untimely filings prior to this suspension hearing, he was not aware of his broker's errors. Judge Randall concluded that this lack of knowledge logically negated any inference that Mediplas was intentionally failing to inform the DEA of the incoming shipments. Judge Randall noted Mediplas did not fail to notify the DEA of the two shipments at issue, but that the notifications were late. Thus, Judge Randall found it significant that Mediplas's obvious intent was compliance rather than deception in response to this legal requirement.

The Government agrees in its Exceptions that in a prior DEA case, the Deputy Administrator found a DEA registrant responsible for the unlawful actions of its employee, even though the registrant claimed it had no knowledge of the unlawful acts, citing *Leonard Merkow, M.D.,* 60 FR 22,075 (1995). The Deputy Administrator agrees with the Government, and finds in the context of this case that Mediplas is liable for the negligent acts of its agent occurring within the scope of the agent's authority where Mediplas as principal had a statutory and regulatory duty to give 15-day advance notice of importation of a listed chemical. 21 U.S.C. 971(a); 21 CFR 1313.12. *See Restatement (Second) of Agency,* Sections 272, 275, and 277 (1958). See also W. Seavey, *Law of Agency,* Section 98 (1964). Since the Deputy Administrator finds Mediplas is liable in this case for its agent's failure to timely file eight 486 forms, the late-filed forms must weigh negatively in assessing Mediplas's compliance with the obligations of a DEA registrant. Pursuant to the *Suspension of Shipments Cases* ruling, however, these late-filed 486 forms do not in themselves justify issuance of the suspension orders in this case.

The record also contains evidence that Mediplas imported pseudoephedrine without a modified Certificate of Registration from the DEA. Specifically, Mediplas was authorized by DEA on April 10, 2000, to import pseudoephedrine. Yet Mediplas's pseudoephedrine product was found at clandestine methamphetamine laboratory sites as early as March 28, 2000. Further, the DEA had a letter from Mediplas dated February 15, 2000, recording the arrival and sale of Mediplas's pseudoephedrine product. Thus, Judge Randall found Mediplas initially imported its paragraph product with the DEA's knowledge that it lacked DEA's authorization, in the form of a modified Certificate of Registration reflecting the addition of pseudoephedrine to the list of controlled chemicals Mediplas was authorized to import. Judge Randall noted the record contains no evidence that the DEA informed Mediplas of (1) its failure timely to obtain the appropriate registration or (2) of the fact that the DEA found Mediplas's pseudoephedrine product at clandestine laboratory sites prior to Mediplas obtaining the requisite registration. The record does contain letters from Mr. Ahmed, voluntarily informing the DEA of his importation and sales of pseudoephedrine product between February and April of 2000. Judge Randall concluded that Mr. Ahmed was not trying to avoid DEA regulatory requirements or in any way to deceive the DEA.

Looking at the totality of these circumstances, Judge Randall concluded that Mediplas's failure to timely modify its registration, balanced by Mediplas's voluntary compliance efforts, did not justify the suspension of these two shipments. The Government in its Exceptions argues *inter alia* that it should not share the responsibility for a registrant's actions taken outside the scope of the registrant's authority.

The Deputy Administrator finds that evidence of voluntary communications received by DEA from a registrant are admissible to show attempted compliance with applicable DEA registrant obligations. Lack of a DEA response to such voluntary communications, however, does not serve to ratify or to otherwise authorize illicit or unauthorized acts by the registrant. DEA regulations clearly state that ''[e]very person who * * * imports * * * any List I chemical * * * shall obtain annually a registration specific to the List I chemicals to be handled[.]'' 21 CFR 1309.21(a). In addition, ''a person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.'' 21 CFR 1309.22(b). Finally, ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is approved and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1309.31(a). Mediplas violated these regulations by importing and distributing pseudoephedrine on two occasions without being properly registered to do so.

The Deputy Administrator concurs with Judge Randall's conclusion that Mediplas was not trying to avoid DEA regulatory requirements or to deceive the DEA. Mediplas's efforts to comply with the obligations of a DEA chemical registrant were both extensive and laudable. The Deputy Administrator finds, however, that the record shows the violations set forth above were attributable to a lack of proper care and attention on the part of Mediplas. The Deputy Administrator is therefore forced to conclude that the untimely Form 486 filing violations attributable to Mediplas, together with Mediplas's multiple regulatory violations regarding its premature importations and distributions of pseudoephedrine, ultimately contribute to the finding herein that the suspended shipments at issue may be diverted.

The Deputy Administrator further notes with regard to the instant case that efforts at compliance are ultimately irrelevant to the specific determination of whether a chemical shipment may be diverted. As previously stated, a suspension order may be justified without regard to culpability. Remedial efforts by a regulated person to whom such an order applies, however, could well be relevant to this determination. The Deputy Administrator notes Judge Randall found Mr. Ahmed credibly testified that, in a letter sent to the DEA Headquarters dated July 12, 2002, he had sought guidance from DEA concerning how to respond to the Warning Letters he received. Specifically, Mr. Ahmed provided a number of proposals for the DEA's approval, to include (1) Mediplas would discontinue the sale and import of pseudoephedrine, (2) Mediplas would reduce its imported amount of ephedrine per month, (3) Mediplas would repackage its product into ''pouch packs,'' and (4) Mediplas would discontinue sales to Wholesale Outlet, selling instead to another distributor. In addition, pursuant to his reconsideration of the *Suspension of Shipments* evidentiary ruling, the Deputy Administrator has considered a letter dated August 15, 2000, from Mr. Ahmed to DEA wherein Mr. Ahmed states he is holding the sale of the two shipments, and that he has stopped the importation of his Twin-Pseudo product. The Deputy Administrator finds that, while this evidence shows that Mediplas appears to be willing to take extensive remedial actions in an effort to thwart future diversion, without additional evidence establishing concrete remedial steps taken, this evidence is insufficient to mitigate the conclusion that the suspended shipments at issue may be diverted.

Pursuant to his reconsideration of the evidentiary ruling in the *Suspension of Shipment Cases* above, the Deputy Administrator has also considered a Government exhibit representing he results of the previously-mentioned DEA audit of Wholesale Outlet's List I chemical products that was conducted subsequent to the date of the OTSS. The audit covered the time period from September 22, 1998, to September 22, 2000, and focused on the accountability of List I chemicals supplied to Wholesale Outlet by Mediplas, as well as List I chemicals supplied to Wholesale Outlet by at least six additional suppliers. The audit revealed numerous dosage unit shortages and overages of various List I chemical products supplied to Wholesale Outlet by Mediplas. The audit also revealed numerous shortages and overages of List I chemical products supplied to Wholesale Outlet by the other six suppliers. There were shortages and overages in every List I chemical product audited, including each of Mediplas's List I chemical products supplied to Wholesale Outlet. Wholesale Outlet failed to account for various List I chemical products ranging from the hundreds to almost two million dosage units, depending on the product. The recordkeeping discrepancies for Mediplas products alone reached almost to eleven million dosage units of List I chemical products.

List I chemical recordkeeping discrepancies constitute violations of 21 U.S.C. 830(a) and 842(a)(10) and 21 CFR 1310.03 and 1310.06. The Deputy Administrator finds that the results of this audit constitute substantial evidence showing Wholesale Outlet's significant failures to comply with applicable recordkeeping requirements, creating a grave risk of diversion. *See Alexander Drug Company, Inc.* 66 FR 18,299, 18,303 (2001). Therefore, the Deputy Administrator finds that the results of this audit weigh heavily in favor of a determination that the suspended chemicals may be diverted.

As further justification in issuing the OTSS in this case, the Government provided data concerning Mediplas's sales figures and the sales figures of a major distributor of pseudoephedrine products, Warner Lambert. The record shows that Mediplas distributed to Wholesale Outlet 135,094 bottles, or 16,211,280 dosage units, of List I chemical products between February 7 and March 1, 2000; while Warner Lambert distributed 38,287,089 dosage units of List I chemical products for the entire year of 1997. Judge Randall construed the Government's argument to suggest that, because Mediplas's sales figures seemed so disproportionately high compared to Warner Lambert's figures, that the sales were ''suspicious'' or otherwise led to a conclusion that Mediplas product were more likely to be diverted than Warner Lambert's product. Judge Randall concluded that this logic is not supported by the record because the Government provided no data of diverted product from Warner Lambert and therefore the basis for a complete comparison does not exist.

In its Exceptions, the Government states that the purpose of this evidence is not to make a relative comparison of the likelihood of diversion of Mediplas versus Warner Lambert products. Rather, the Government seems to argue that this evidence is relevant to the ''may be diverted'' standard because of the large amount of chemicals sold by a relatively small company over a short period of time could saturate the market and create an environment conducive to diversion.

The Deputy Administrator concurs with Judge Randall's finding that the statute and regulations provide quantity amounts of List I chemicals to define a ''regulated transaction.'' *See* 21 U.S.C. 802(39)(a); 21 CFR 1300.02(28) and 1310.04. If a ''regulated person'' engages in a ''regulated transaction,'' then such

a transaction triggers recordkeeping and reporting requirements. *See* 21 CFR 1310.04 and 1310.05. Neither the statute nor the regulations provide limitations on the amount of List I chemicals a registered importer may sell to a registered distributor in the normal course of business.

The Deputy Administrator disagrees with the Government, and concurs with Judge Randall's determination that there is insufficient evidence in the record to find that the quantity of List I chemical products distributed by Mediplas over the above-referenced time period was an ''extraordinary quantity.'' The Deputy Administrator also concurs with judge Randall's finding that the record contains no evidence that the quantities of List I chemicals sold to Wholesale Outlet by Mediplas violated any published regulations or other materials distributed by DEA to its business registrants. The Deputy Administrator notes the Government does not argue that Mediplas had any specific recordkeeping or reporting discrepancies, even though Government witnesses asserted that Mediplas engaged in ''excessive quantity'' sales.

The Deputy Administrator notes that nowhere in the law, regulations, or in DEA guidelines is ''extraordinary quantity'' defined or discussed. The Deputy Administrator further notes that, while Mediplas may be a small company distributing to a single customer, that customer, Wholesale Outlet, had in turn approximately 200 of its own customers across the United States. The record shows that a number of these customers were distributors and wholesalers in their own right. The record further shows that Mr. Ahmed was aware of Wholesale Outlet's extensive distribution network, and this was a significant reason why he chose to do exclusive business with Wholesale Outlet. As to the Government's ''market saturation'' argument, the Government presented no evidence purporting to show that Wholesale Outlet's distribution network was inadequate to legitimately absorb the quantity of List I chemical products received from Mediplas.

Likewise, the record contains no evidence that Mediplas sold unauthorized quantities of List I chemicals to Wholesale Outlet. Although several Government witnesses testified that Mediplas engaged in sales of excessive quantities, the Deputy Administrator concurs with Judge Randall's finding that the bases of their conclusions are speculative. The Government has provided insufficient evidence to support its conclusion that such sales of listed chemicals in such a business setting would equate to ''excessive quantities.'' Therefore, the Deputy Administrator concurs with Judge Randall's finding that the Government's ''excessive quantities'' arguments are not persuasive under the circumstances of this case. Accordingly, the Deputy Administrator further agrees with Judge Randall's conclusion that the quantities Mediplas sold in the normal course of business do not serve as grounds to believe that the two shipments at issue ''may be diverted.''

As additional justification for the OTSS, several Government witnesses testified concerning the ''traditional'' market and the ''non-traditional'' market for products containing ephedrine and pseudoephedrine. This testimony, supported only by anecdotal evidence, is as follows. The ''traditional'' market includes outlets where a consumer of such legitimate over-the-counter products containing ephedrine or pseudoephedrine would be expected to purchase them. Such outlets would include pharmacies, or pharmacy sections of grocery stores, or discount stores such as Wal Mart. In contrast, the ''non-traditional market'' includes outlets where a consumer of such legitimate over-the-counter products containing ephedrine or pseudoephedrine would be less likely to purchase them. Such market outlets would include convenience stores, liquor stores, and gas stations. The ''traditional'' market and the ''non-traditional'' market also differ in the packaging of over-the-counter ephedrine and pseudoephedrine products. Outlets in the ''traditional'' market typically sell such over-the-counter products packaged in blister packs, in 24-count or 48-count packages sizes. The ''non-traditional'' market outlets, on the other hand, tend to sell over-the-counter products containing ephedrine and pseudoephedrine in bottles, typically of 60-count or 120-count size. Several Government witnesses testified that ephedrine and pseudoephedrine products found at larger illicit methamphetamine laboratories are usually packaged in the 60-count and 120-count bottles. The DEA therefore concludes that the source of these bottles is the ''non-traditional'' market outlets. The DEA has also found such packaged pseudoephedrine products at methamphetamine laboratory dump sites.

The Deputy Administrator notes, however, that a Government witness also testified that List I chemical products distributed through the traditional market, such as through Wal-Mart, have also be diverted. Upon cross examination, a Government witness admitted that the ''traditional'' versus ''non-traditional'' outlet distinction was an informal, internal DEA use only. As of the date of the hearing, the DEA had not recorded such distinctions in any of its regulations. The Deputy Administrator finds the probative weight of this evidence is minimal without some form of further extrinsic evidence to support these arguments.

Upon reviewing the totality of the circumstances of this case, the Deputy Administrator finds the OTSS justified. In reaching this conclusion, the Deputy Administrator has carefully considered Mediplas's exemplary efforts to comply with its obligations as a DEA chemical registrant, as well as its extensive record of cooperation with the DEA. The Government provided ample evidence to show these shipments may be diverted, however. The record shows that at the time of the hearing, Mediplas's immediate and sole customer, Wholesale Outlet, was under investigation by DEA regarding suspected misconduct in its handling of List I chemicals, and was also the subject of a DEA criminal search warrant, based upon probable cause to believe it was engaged in misconduct in handling List I chemicals. A DEA audit of Wholesale Outlet found numerous and enormous shortages and overages of *inter alia* Mediplas's List I chemical products. In addition, the nine Warning Letters issued to Mediplas documented thousands of bottles of Mediplas's List I chemical products being diverted to the clandestine manufacture of controlled substances.

The record shows, moreover, that Mediplas significantly violated applicable law and regulations by, first, failing to timely file eight Form 486 advanced notifications of importations; and second, by importing and distributing the List I chemical pseudoephedrine on two occasions, without obtaining proper registration.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 971 and 28 CFR 0.100(b), hereby orders that the suspensions of the subject shipments be, and hereby are, sustained.

This final order is effective immediately.

Dated: May 30, 2002.

John B. Brown III,

Deputy Administrator.

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