Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: Unified Abrasive Manufacturers Association, Cleveland, OH. The nature and scope of UAMA's standards development activities are: UAMA acts as secretariat for two ANSI accredited standards committees which develop (1) specifications for safety in the use of bonded, coated and loose abrasives, excluding natural sandstones, including safety requirements for abrasive products, abrasive machines and accessories, and requirements for the proper storage, handling and mounting of abrasive products; and (2) identification and dimensional standards and standard test methods for bonded, coated and loose abrasive in the natural and manufactured categories.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–25859 Filed 11–19–04; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Video Electronics Standards Association

Notice is hereby given that, on September 20, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Video Electronics Standards Association (''VESA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: Video Electronics Standards Association, Milpitas, CA. The nature and scope of VESA's standards development activities are: To facilitate and promote personal computer graphics through improved graphics standards for the benefit of the end user; to support and set industry-wide interface standards for the personal computer, workstation and computing environments; and to promote and develop timely, relevant, open standards for the display and display interface industry, ensuring interoperability and encouraging innovation and market growth.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–25843 Filed 11–19–04; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Window & Door Manufacturers Association

Notice is hereby given that, on September 21, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Window & Door Manufacturers Association (''WDMA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principle place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provision limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: Window & Door Manufacturers Association, Des Plaines, IL. The nature and scope of WDMA's standards development activities are: WDMA develops voluntary consensus industry standards pertaining to the design and manufacture of products, and the components of the products, of the window, skylight and door industry. WDMA is currently recognized by the American National Standards Institute (ANSI) as an Accredited Standards Developing Organization (SDO).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–25870 Filed 11–19–04; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 01–12; 01–13]

Indace, Inc., c/o Seegott, Inc.; Malladi, Inc.; Suspension of Shipments

On January 25, 2001, the then-Administrator of the Drug Enforcement Administration (DEA) issued an Order to Suspend Shipment to Indace, Inc., c/o Seegot, Inc. (Indace) of Elgin, Illinois, notifying it that pursuant to 21 U.S.C. 971, DEA had ordered the suspension of a shipment of 3,000 kilograms of ephedrine hydrochloride, a listed chemical, from India into the United States. Indace indicated in its request for importation that the listed chemical was intended for further shipment to PDK Laboratories, Inc. (PDK) of Hauppage, New York. The Order to Suspend Shipment stated that DEA concluded that the listed chemical may be diverted to the clandestine manufacture of a controlled substance based upon the appearance of products manufactured from prior imports of ephedrine and pseudoephedrine destined for PDK at illicit criminal sites, including methamphetamine clandestine laboratories and dumpsites throughout the United States.

On January 26, 2001, the then-Administrator of DEA issued an Order to Suspend Shipment to Malladi, Inc. (Malladi) of Edison, New Jersey, notifying it that pursuant to 21 U.S.C. 971, DEA had ordered the suspension of a shipment of 3,000 kilograms of ephedrine hydrochloride, a listed chemical, from India into the United States. Malladi also had indicated in its request for importation that the listed chemical was intended for further shipment of PDK and the Order to Suspend Shipment similarly stated that DEA had concluded the listed chemical may be diverted to the clandestine manufacture of a controlled substance, based upon the appearance of products manufactured from prior imports of ephedrine and pseudoephedrine destined for PDK at illicit criminal sites, including methamphetamine clandestine laboratories and dumpsites throughout the United States.

On February 8, 2001, PDK requested a hearing in both matters, asserting standing as a Respondent pursuant to the ruling in *PDK Laboratories, Inc.* v. *Reno,* et al., 134 F.Supp.2d 24 (D.D.C. 2001). DEA complied with the District Court's ruling and both matters were docketed before Administrative Law Judge (ALJ) Gail A. Randall.

On March 8, 2001, the ALJ issued an order consolidating both matters for hearing purposes. Neither Indace nor Malladi requested a hearing in these matters. Following prehearing procedures, a hearing was held in Arlington, Virginia, on March 26–30, April 5–6, April 11–13 and April 16–17, 2001. At the hearing, PDK and the Government called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law, and argument.

On April 5, 2002, the ALJ issued a consolidated Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter ''Recommendation'' or ''Opinion and Recommended Ruling'') recommending that both suspensions be lifted and the exporters allowed to complete the shipments. On April 25, 2002, the Government filed Exceptions to the ALJ's Recommendation. In response, on May 21, 2002, PDK filed its Response to the Exceptions Filed by the Government. Subsequently, on June 5, 2002, the ALJ transmitted the record of these proceedings to the Deputy Administrator for final action pursuant to 21 CFR 1313.57.

On December 13, 2002, pursuant to 21 CFR 1313.57, then-Deputy Administrator John B. Brown III, issued his final order regarding the Indace and Malladi suspensions of shipments. The then-Deputy Administrator rejected the Opinion and Recommended Ruling of the Administrative Law Judge. That final order was subsequently published in the **Federal Register** on December 19, 2002. *See* Indace, Inc. c/o Segott, Inc.; Malladi, Inc. (Indace/Malladi), 67 FR 77805 (2002).

In the ALJ's Opinion and Recommended Ruling, she interpreted the terms''listed chemical'' and ''the chemical,'' as set forth in 21 U.S.C. 971(c)(1) (hereafter ''971''), to be limited to the actual material to be imported, in this case, bulk ephedrine. In the event the Deputy Administrator disagreed with that interpretation, the ALJ made alternative findings and recommendations that the Government had not satisfied the ''may be diverted'' portion of 971. The then-Deputy Administrator rejected the ALJ's interpretation of 971, finding:

> The application of 971 is not limited to the imported form of the listed chemical. The Deputy Administrator concludes that the provisions of 971 apply to regulated transactions involving listed chemicals regardless of imported or exported form. *i.e.,* bulk of finished products. The Deputy Administrator further concludes the provisions of 971 apply to finished products subsequently manufactured from bulk imported list chemicals.

Id., 67 FR at 77806.

The then-Deputy Administrator agreed with the ALJ that the evidence did not show, by a preponderance of the evidence, a violation by PDK of its obligation to report suspicious sales under 21 CFR 1310.05(a)(1) in connection with certain mail order sales of 25 mg. ephedrine products which occurred in 1995 and 1996. The then-Deputy Administrator further noted there had been testimony presented concerning ''traditional'' versus ''non-traditional'' markets for List I chemical products. However, in accord with his previous holding on this subject, he found the probative weight of the evidence introduced in this case to be minimal, without ''some form of further extrinsic evidence to support these arguments.'' Indace/Malladi, *supra,* 67 FR at 77808, quoting Mediplas Innovations, (Mediplas) 67 FR 41256, 41264 (2002).

However, relying primarily on the issuance of a series of Warning Letters by DEA between 1999 and 2001, advising PDK that its ephedrine and pseudoephedrine products had been found at illicit methamphetamine manufacturing sites, the then-Deputy Administrator concluded sufficient evidence supported DEA's contention that the chemicals may be diverted. Secondarily, the then-Deputy Administrator relied on PDK's failure to report as exports, pursuant to 21 CFR 1313.21(a), four shipments of ephedrine sold to Sun Labs of Canada between 1994 and 1995, which had been delivered within the United States.

In making his ruling the then-Deputy Administrator applied the ''totality of the circumstances'' test used in Mediplas, stating:

> The Deputy Administrator notes the record is replete with PDK's contentions that it has worked hard to evaluate its activities and to cooperate with DEA in stemming diversion. However, the record shows that diversion of PDK products has continued to occur, and that, based upon the Warning Letters received, PDK should have known its remedial actions were insufficient to stem the diversion of its List I chemical products. Moreover, the record shows evidence that PDK violated export regulations on at least four occasions by failing to file the required notifications of its shipments to Sun Labs. The totality of the circumstances therefore supports the Government's assertion that the list chemicals sought to be imported and distributed to PDK may be diverted and furthermore that the Suspension Orders were proper and should be sustained, Mediplas, 67 FR at 41,264. The fact that PDK products containing ephedrine and pseudoephedrine have been repeatedly found at the site of clandestine methamphetamine laboratories and dump sites is a significant indicator that these products may continue to be diverted to such illicit activities.
>
> * * * The Deputy Administrator finds that there was sufficient evidence at the time of the hearing to support DEA's contention that the chemicals may be diverted. Mediplas, 67 FR at 41260–41261 * * * Therefore, the Deputy Administrator concludes that the suspensions set forth in the January 25 and 26, 2001 Orders to Suspend Shipments of ephedrine hydrochloride issued to Indace and Malladi were justified.

Indace/Malladi, *supra,* 67 FR at 77809.

PDK filed a timely petition for review of the final order pursuant to 21 U.S.C. 877 with the United States Court of Appeals for the District of Columbia Circuit and on March 26, 2004, the Court issued its opinion in *PDK Laboratories Inc.* v. *U.S. Drug Enforcement Administration (PDK Labs),* 362 F.3d 786 (D.C. Cir. 2004). Consistent with the District Court's decision in *PDK Labs Inc.* v. *Reno, supra,* 134 F. Supp. at 31, the Court of Appeal concluded PDK had both prudential and Article III standing to challenge the suspension orders under the facts and circumstances of this cas. PDK Labs, *supra,* 363 F.3d at 791–794; *see also PDK Labs Inc.* v. *Ashcroft,* ____ *F.Supp.2d* ____, 2004 WL 1924930, 4 (D.D.C., decided August 27, 2004).

The Court of Appeal also ruled that the final order of December 13, 2002, should be set aside and remanded to DEA for a new final order. The entire Court concluded the then-Deputy Administrator had relied in significant part on PDK's failure to file export notifications regarding the New York deliveries of tablets containing ephedrine to Sun Labs of Canada. However, the final order failed to distinguish or explain its apparent departure from the position taken by the agency in Alfred Khalily, Inc. (Khalily), 64 FR 31289 (DEA June 10, 1999). PDK Labs, 363 F.3d at 798–799.

> In applying his 'totality of the circumstances' approach to determining whether the listed chemical may be diverted, the Deputy Administrator ruled that PDK had violated an export notification regulation when it made four deliveries of tablets containing ephedrine between 1994 and 1995 to Sun Labs of Canada in New York. 67 FR

at 77807–08. The Deputy Administrator did not explain how alleged export violations were relevant to determining whether PDK's finished products might be used in methamphetamine laboratories. In any event, the Deputy Administrator failed to distinguish, indeed did not mention, Alfred Khalily, Inc., 64 FR 31389 (DEA June 10, 1999), which held that a company selling List I chemicals to a foreign buyer but delivering the chemicals to the buyer in the United States 'was not responsible for filing any export documentation.' *Id.* at 31,293 n.2.

PDK Labs, 362 F.3d at 788.

In addition to this ground for remand, a majority of the Court also concluded that remand was necessary for DEA to interpret 971(c)(1)'s provision authorizing DEA to ''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.'' *See PDK Labs,* v. *DEA*, 362 F.3d at 794–98. One judge issued a concurring opinion which, while agreeing remand was appropriate for the failure to distinguish Khalily, disagreed with the majority as to the need for DEA to provide further interpretation of section 971(c)(1). *Id.* at 799–810 (Roberts, J., conc.). However, the majority analyzed the crux of the case as follows:

> The main interpretive question in the case is whether, as the suspension orders assume, 'the chemical may be diverted' includes the prospect that PDK's ephedrine-containing pills in retail stores will be sold to, or shoplifted by, people who will then use the pills to produce methamphetamine [fn]. The Deputy Administrator concluded that the statute plainly meant what the suspension orders assumed. He reached this conclusion without mentioning any policy considerations or other means within the agency's expertise. Apparently for this reason, DEA neither invoked *Chevron* v. *NRDC,* U.S. 837, 843–45 (1984), nor asks us to give special deference to the Deputy Administrator's judgment about the meaning of the provision.

PDK Labs, *supra,* 362 F.3d at 794.

The majority viewed the then-Deputy Administrator's final order as premised on an erroneous belief that the statute was ''clear'' and 971(c)(1)'s meaning ''plain.'' *Id.*, at 794–95. It held as follows:

> We do not agree that the language of § 971(c)(1) *plainly* covers the diversion of finished products, or drug products. That a statute is susceptible of one construction does not render its meaning plain if it is also susceptible of another plausible construction, as we believe this statute is. Section 971(c)(1) deals with importation (and exportation) of listed chemicals. It does not regulate what a drug manufacturer does with the chemical after receiving it; other sections of the [Controlled Substances Act, as amended] control that subject. When § 971(c)(1) states that DEA may stop the importation if 'the chemical may be diverted to the clandestine manufacture of a controlled substance,' one might ask: 'Diverted from what?' In context, a reading as plausible as the Deputy Administrator's is that Congress meant only to cover diversions during importation. On this view, § 971(c)(1) would authorize suspension orders only if the imported chemical might not reach its intended destination—the legitimate, domestic manufacturer.

PDK Labs, *supra,* 362 F.3d at 796–97 (italics in original).

The majority further concluded,

> In short, we do not agree that the meaning of § 971(c)(1) is as plain as it says it is. It may be that here, as in other cases, the strict dichotomy between clarity and ambiguity is artificial, that what we have here is a continuum, a probability of meaning. In precisely those kinds of cases, it is incumbent upon the agency not to rest simply on its parsing of the statutory language. It must bring its experience and expertise to bear in light of competing interests at stake. See *Chevron* v. *NRDC,* 467 U.S. at 865–66, 104 S. Ct. at 2792–93. But it has not done so here and at this stage it is not for the court 'to choose between competing meanings.' [Citations].

PDK Labs, *supra,* 362 F.3d at 797–98.

With this guidance in mind, the Deputy Administrator has considered the record in its entirety, along with the Court of Appeal's ruling and, pursuant to 21 CFR 1313.57, hereby issues her final order regarding the Indace and Malladi suspension of shipments, based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator is issuing one final order regarding both suspension cases since the same findings of fact and conclusions of law apply to both suspensions. Except as hereinafter noted, the Deputy Administrator rejects, in its entirety, the Opinion and Recommended Ruling of the Administrative Law Judge. Based upon her review of the record in this matter, including all submissions of both parties, and exceptions as filed, the Deputy Administrator adopts such findings of fact and conclusions of law as hereinafter follow.

The Deputy Administrator finds that both Indace and Malladi are registered with DEA as importers of listed chemicals. Both importers were advised in the Orders to Suspend Shipment of their right to request a hearing. Neither importer chose to do so. Furthermore, the record reflects that the ALJ gave Indace an opportunity to participate in prehearing matters, but Indace did not respond. Accordingly the Deputy Administrator concludes that both Indace and Malladi have waived their right to a hearing pursuant to 21 CFR 1313.54.

It is now the law of the case that in reference to this proceeding, PDK is ''a regulated person to whom an order applies under 21 U.S.C. 971(c)(2) with respect to the suspension of List I chemicals to be imported on PDK's behalf.'' *PDK Laboratories Inc.* v. *Reno,* et al., *supra,* 134 F.Supp. at 31; PDK Labs, *supra,* 362 F.3d at 792–95. Accordingly, the District Court and the Court of Appeal have created a rule for this case.[1]

On January 25 and 26, 2001, DEA issued the Orders to Suspend Shipment to Indace and Malladi which are the subject of these proceedings. The Orders asserted as a basis for suspension that the ephedrine to be imported may be diverted to the illicit production of a controlled substance. They recited that DEA investigations revealed that products produced from prior imports of ephedrine and pseudoephedrine destined for PDK had appeared at clandestine methamphetamine laboratories in the United States. The Orders also indicated that traffickers utilize ephedrine and pseudoephedrine in the illicit production of methamphetamine, that PDK manufactures and distributes over-the-counter drug products containing the listed chemicals pseudoephedrine and ephedrine, that these products are distributed in strength, quantity and packaging unlike the traditional market (referred to by DEA as ''gray market'' products), and that these products are generally distributed and sold through non-traditional retail outlets. The Orders to Suspend Shipment also indicated that DEA data regarding clandestine laboratory seizures noted that gray market products are predominantly encountered in clandestine methamphetamine laboratories.

The issue before the Deputy Administrator is whether or not the record as a whole establishes by a preponderance of the evidence that DEA should suspend the two shipments of ephedrine hydrochloride destined to be shipped from India to the United States, pursuant to 21 U.S.C. 971(c)(1) and 21 CFR 1313.41(a).

[1] However, as the Court of Appeal indicated, ''in holding that PDK has prudential standing, we have avoided placing a judicial interpretation on § 971(c)(2), the hearing provision.'' PDK Labs, *supra,* 362 F.3d at 794. The Deputy Administrator therefore declines to adopt a rule as DEA policy that a party in PDK's position (*i.e.,* a wholesale distributor/manufacturer or a downstream customer of such an entity), is entitled to a hearing under 21 U.S.C. 971(c)(2) as a ''regulated person to whom an order applies under paragraph (1)'' of that subdivision.

There is no evidence that the shipments of bulk ephedrine hydrochloride would be diverted before reaching PDK, the intended recipient within the United States. Thus, if the ALJ's interpretation of the terms ''listed chemical'' and ''the chemical'' as set forth in 971(c)(1) was correct, the suspensions could not be sustained. However, the Deputy Administrator rejects the ALJ's interpretation of these critical terms and concludes they encompass more than just the imported or exported form of the listed chemical, in this case bulk ephedrine hydrochloride. Instead, the Deputy Administrator finds the applicable provisions of 971 apply to regulated transactions involving listed chemicals, regardless of their imported or exported form, *i.e.*, bulk or finished products. The Deputy Administrator further concludes the terms at issue also apply to finished products subsequently manufactured from bulk imported/exported list chemicals.

The Deputy Administrator believes that the term ''listed chemical,'' as used in 971(c)(1) should be construed broadly in light of that term's use in other parts of the same statute, which was enacted by Congress in 1988. In the previous final order, the then-Deputy Administrator cited the Ninth Court of Appeal's decision in *United States* v. *Daas (Dass)*, 198 F.3d 1167 (9th Cir. 1999). *See*, Indace/Malladi, 67 FR at 77806. In that case, the defendant, who had been convicted under then-21 U.S.C. 841(d)(2)[2] for distributing a listed chemical, argued the evidence was insufficient to support his conviction because that statute, which was enacted at the same time as 971(c)(1), only criminalized the distribution of pure ephedrine or pseudoephedrine, not a chemical mixture containing these chemicals.

The Ninth Circuit rejected that argument, holding that ''§ 841(d)(2) encompasses such mixtures as Mini Thins and Pseudo Thins.'' Dass, 198 F.3d at 1174. In particular, the Ninth Circuit noted that the ephedrine and pseudoephedrine in Mini Thins and Pseudo Thins ''retain a separate existence,'' (quoting *Chapman* v. *United States*, 500 U.S. 453, 461 (1991) and, therefore, that ''[t]he ephedrine and pseudoephedrine in Mini Thins and Pseudo Thins are plainly 'listed chemicals' within the meaning of § 841(d)(2).'' *Id.*, at 1175.[3]

For clarification, while Daas referred to the ''plain'' meaning of the phrase in the criminal statute, the Deputy Administrator does not view Dass as *mandating* the adopted interpretation of 971(c)(1). However, as noted by the majority in PDK Labs, ''There is logic in the Ninth Circuit's reasoning, and in the Deputy Administrator's reliance on the decision. When Congress uses the same word in different parts of a statute, it usually means the same thing. *See Sullivan* v. *Stroop*, 496 U.S. 478, 484 (1990); *Energy Research Found* v. *Defense Nuclear Safety Bd.*, 917 F.2d 581, 583 (D.C. Cir. 1990).'' PDK Labs, 362 F.3d at 796.

However, the majority went on to note that logic is only one component of statutory interpretation. The words of the statute should be ''read in context, the statute's place in 'the overall scheme' should be considered, and the problem Congress sought to solve should be taken into account [Citations].'' PDK Labs, 362 F.3d at 797.

The Deputy Administrator finds that based upon the evidence in the record, the listed chemicals ephedrine and pseudoephedrine are marketed in prescription and over-the-counter drug products which have legitimate therapeutic uses as a bronchodilator and nasal decongestant, respectively.

The Deputy Administrator also finds that over the past decades, DEA has been engaged in enforcement and regulatory activity to control the large-scale diversion of chemicals, including ephedrine and pseudoephedrine, into the illicit manufacture of controlled substances. The controlled substance methamphetamine is easily produced in clandestine laboratories using either pseudoephedrine or ephedrine. The process of manufacturing methamphetamine is easily accomplished with minimal equipment and readily available chemical supplies.

The Controlled Substances Act has always prohibited the illicit (*i.e.*, without a DEA registration) manufacture of controlled substances. The earliest illicit methamphetamine laboratories used the freely available chemical phenyl-2-propanone, also known as phenylacetone or P2P, to produce methamphetamine, until that substance was itself scheduled as a controlled substance. In the 1980's methamphetamine laboratories increasingly began to switch to an ephedrine process. The Chemical Diversion and Trafficking Act of 1988 (CDTA), Pub. L. 100–690, established the basic scheme of chemical regulation and imposed reporting and record keeping and import/export notification requirements on certain regulated transactions involving chemicals, including bulk ephedrine. However, at the time, listed chemicals contained in drug products were exempted from the reporting and record keeping provisions of the CDTA.

In response to these controls, illicit methamphetamine laboratories began to switch to targeted ''single entity'' ephedrine as a raw material. The Domestic Chemical Diversion Control Act of 1993 (DCDCA), Pub. L. 103–200, was then crafted to close the ephedrine ''loophole'' by removing the exemption for ''single entity'' ephedrine products, and lowering its sales threshold. In addition, the DCDCA initiated a registration requirement for handlers of List I chemicals.

Subsequently, illicit laboratories shifted to pseudoephedrine and combination ephedrine drug products as sources of raw material, prompting the passage of the Comprehensive Methamphetamine Control Act of 1996 (MCA), Pub. L. 104–237, to establish additional controls and quantity thresholds for reporting transactions regarding listed chemicals. The MCA also established a Suspicious Orders Task Force, in part to assist in alerting the chemical industry to the many devices used by individuals who seek to divert large quantities of listed chemicals and listed chemical products into the illicit manufacture of controlled substances.

Thus, there has been a series of legislative enactments intended to address the problems of illicit drugs, including methamphetamine. As illicit manufacturers altered methods of production and choices of precursor chemicals, Congress enacted legislation intended in significant part to brunt the efforts of criminals engaged in operating clandestine methamphetamine laboratories and to thwart or impede their obtaining the precursor chemicals required to manufacture controlled substances.

The Deputy Administrator finds nothing in the legislative history of these enactments compels the narrow interpretation of 971(c)(1) adopted by the ALJ in her Opinion and Recommended Ruling. Indeed, that history suggests Congress was very much concerned with the diversion of finished drug products containing ephedrine. *See* H.R. Rep. No. 103–

[2] Now 21 U.S.C. 841(c)(2).

[3] The Mini-Thin ephedrine based product involved in Daas, had been obtained by the defendant from Body Dynamics Incorporated (BDI) and sold to the All-Rite Market of Marysville, California between early 1996 and early 1997. Daas, *supra*, 198 F.3d at 1171–72. During this period, PDK was manufacturing the Mini-Thin products and distributing it exclusively through BDI. In 1998, after DEA executed a Federal search warrant on BDI and sent a Warning Letter to PDK concerning BDI labeled products being found at illicit sites, PDK terminated its contract with BDI.

379(I), at 6 (1993), reprinted in 1993 U.S.C.C.A.N. 2983 [''This provision removes the exemption * * * for drugs containing ephedrine * * * because these products are being diverted in significant quantities for the illicit manufacture of methamphetamine''). As discussed in the initial final order, when the then-Acting Deputy Administrator made a report to the House of Representatives Committee considering the DCDCA, it indicated the legislation was intended, part, to close a ''loophole'' for those who divert ephedrine drug products. *Id.*, at 5, 8 (1993).

As noted by the concurring opinion in PDK Labs, the DEA Acting Administrator's report to the House explained that ''the so-called 'legal drug exemption' which currently exempts drug products approved for marketing under the Food, Drug and Cosmetic Act from the regulatory provisions of our chemical control law had become a 'loophole' exploited by clandestine laboratory operators. H.R. Rep. No. 103–379, at 8. It is that loophole that the DCDCA and CMCA revoked for drugs containing ephedrine, see 21 U.S.C. 802(39)(A)(iv)(I)(aa).'' PDK Labs, 362 F.3d at 803 (Roberts, J., conc.) (internal quotation marks omitted).

However, the majority in PDK Labs observed that the 1993 House Report came out five years after the 1988 enactment of 971(c)(1), that the DCDCA did not specifically amend section 971 and the ''loophole'' being closed concerned record keeping and reporting requirements. PDK Labs, 362 F.3d at 794–95.

Nevertheless, the Deputy Administrator views the totality of these progressive enactments as part of an overall continuum of Congress' intent to provide DEA the regulatory means to monitor the domestic production, manufacture and distribution of List I chemicals and prevent their illicit use in manufacturing methamphetamine, including the ability to prevent the importation of bulk chemicals that will be manufactured into chemical products after arriving into the United States and then diverted throughout the country to thousands of clandestine laboratories.

The Deputy Administrator does not view the relevant enactments of Congress as expressing any clear intent that the term ''listed chemical,'' as used in 971(c)(1), was limited to the particular chemical being imported or that DEA, as the agency entrusted with administering that provision, could not consider and take action to prevent the import of bulk listed chemicals which were to be manufactured into finished products and then, in the downstream course of commerce, diverted to the illicit production of methamphetamine.

If Congress wanted to make an express distinction between a bulk listed chemical and a finished product in section 971(c), it could have done so. For example, 21 U.S.C. 958(i) is the statute permitting registered manufacturers to challenge an application for a DEA registration that seeks to import bulk controlled substances. That provision explicitly states that it is limited to bulk manufacturers. Congress could have done likewise, but it did not make such a distinction between bulk and finished form list chemicals when it crafted section 971.

The record reflects that once PDK receives its bulk ephedrine, it combines the ephedrine with the decongestant guaifenesin and binders to form a listed chemical product. Throughout this process, the chemical composition of the ephedrine is unaltered. Illicit methamphetamine manufacturers then purchase or steal the tablets and break the finished product down to its component parts. This, in effect, yields the same pure ephedrine that was imported for PDK. In this manner, the listed chemical itself—ephedrine—is diverted to methamphetamine manufacturing. As the concurring opinion described the process in PDK Labs,

> At the time of its 'diversion,' the ephedrine extracted from PDK Mini-Two Way Action is just as much a listed chemical as when it was transported across the high seas in bulk form. Thus, at least insofar as a listed chemical is readily extractable from its finished drug product, the text of section 971(c) treats transactions (including a 'diversion') in that drug as transactions in the listed chemical it contains.
>
> This interpretation comports with common sense. If a methamphetamine manufacturer steals, for the purpose of making methamphetamine, a bottle containing pure ephedrine, or pure ephedrine dissolved in water, or a bottle containing 50 ephedrine and 50 guaifenesin pills, we would not hear an argument that he did not divert a listed chemical because he also diverted a bottle, some water, or some guaifensin. The presence of packaging materials or other extraneous items does not vitiate the existence of the listed chemical. Here, a bottle of PDK Mini Two-Way Action contains pills each consisting of 25 mg of ephedrine and 200 mg of guaifensin and binders. For purposes of Section 971(c), the decongestant and the binders are extraneous materials, no more relevant to the analysis than the bottles and boxes in which the pills are packaged.

PDK Labs, 362 F.3d at 800–801 (Roberts, J., conc.).

The Deputy Administrator agrees with this analogy and finds that it comports with that of the Ninth Circuit in interpreting ''listed chemical'' for purposes of 21 U.S.C. 841(d)(2) (now (c)(2)), discussed earlier. *See United States* v. *Daas, supra*, 198 F.3d at 1174–75.

While Congress may not have been as concerned about the diversion of ephedrine-containing products when it enacted section 971 as it was in the years that followed, as noted in the concurring opinion, '' 'the fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.' *PGA Tour, Inc.* v. *Martin*, 532 U.S. 661, 689 (2001) (internal quotation marks and citations omitted); accord Consumer Elecs. Ass'n, 347 F.3d [291] at 298.'' PDK Labs, 362 at 802–03.

Were the ALJ's strict interpretation of section 971(c)(1) given effect, as a policy matter it would also create an arbitrary dual standard. For example, if a listed chemical is imported in bulk form and if it is a chemical that is not or will not be converted to a drug product, then under 971(c)(1), that chemical may be suspended based upon its diversion during any time in its distribution flow, *i.e.*, from the initial importation downstream to the last retail handler. Under the ALJ's interpretation, however, the suspension statute would be of limited use for those bulk products, such as ephedrine, that could be finished into an over-the-counter drug product somewhere along the distribution chain. In other words, as a matter of law, based solely upon the ALJ's statutory interpretation, once the imported bulk ephedrine is converted into a drug product at some point in the distribution chain, it is no longer subject to being suspended pursuant to section 971(c).

Such an artificial distinction between over-the-counter drug products and other chemicals that will not be converted into any finished drug product is not tenable and is certainly inconsistent with the criminal penalty provisions of the law involving imports. For example, if DEA had facts to show that an importer had reasonable cause to believe that a listed chemical was to be imported, tableted, and distributed to a clandestine laboratory, then the importer would be subject to a lengthy term of imprisonment under 21 U.S.C. 960(d)(3). However, even if DEA knew those same facts, under the ALJ's standard, the import shipment could not be suspended.

For consideration only of the policy issues involved in interpreting 971(c)(1), as opposed to the sufficiency of the evidence to show that in *this* particular case the List I chemical ''may be

diverted,'' (inasmuch as no additional extrinsic evidence was introduced at the hearing regarding the gray market; *see* Mediplas, *supra,* 67 FR at 41264; Indace/Malladi, *supra,* 67 FR 77808), a series of cases decided after this matter was litigated and/or originally acted upon by the then-Deputy Administrator, illustrate the problems DEA, state regulators and law enforcement agencies throughout the country currently face as a result of the proliferation of clandestine laboratories—using precursor chemicals, obtained by theft or purchase of listed chemical products which have often been made from bulk chemicals imported into the United States and then distributed to convenience stores and gas stations as a part of the grey market.

See, e.g., OTC Distribution Co., 68 FR 70538, 70539 (2003) (''Pseudoephedrine bulk powder is usually imported from China or India, tableted by DEA-registered manufacturers, distributed to various distributors, wholesalers and then to retail outlets. Of DEA's approximately 3,500 chemical registrants in 2000, over 3,100 were distributors. While illegal diversion can occur at any point in the distribution chain, it usually occurs after the manufacturer has sold its product to a distributor.''; *see also* Branex Incorporated, 69 FR 8682, 8690–93 (2004); Xtreme Enterprises, Inc., 67 FR 76195, 76196–97 (2002); Sinbad Distributing, 67 FR 10232, 10233–34 (2002). For additional background as to the diversion of List I over-the-counter chemical products after distribution to retail establishments as it bears on DEA's interpretation of 971(c)(1), *see also* DEA's Proposed Rules on Security Requirements for Handlers of Pseudoephedrine, Ephedrine, and Phenylpropanolamine, 69 FR 45616, 45617 (2004).

In sum, DEA and other Federal, State and local law enforcement agencies are faced with a growing problem of listed chemicals being imported into the United States in bulk form, which are then converted into List I chemical products, distributed to the grey market and diverted to illicit production of methamphetamine. Section 971(c)(1) is considered by DEA to be a significant component of the regulatory arsenal given it by Congress to combat this immense and growing public problem.

If the language of a law is ambiguous and there exists two competing reasonable interpretations and the agency interpretation, which best suits its goals, is consistent with the intent of Congress, that interpretation should be granted great deference. Such a construct would be especially true here, because section 971 (similar to many other statutes under the Controlled Substances Act) is remedial and since it was passed to protect the public interest, it should be construed broadly to effectuate its purpose. *See Jefferson County Pharmaceutical Association* v. *Abbott Laboratories* et al., 460 U.S. 150, 159 (1983) (holding that the Robinson-Patman Act had to be construed liberally and broadly to effectuate its purpose, which was to prevent anti-trust price discrimination); *Federal Trade Commission* v. *Mandel Brothers, Inc.,* 359 U.S. 385, 389 (1959) (holding that the Federal Trade Commission's interpretation of a retail labeling act would be upheld because the legislation was remedial, *i.e.,* it was enacted to protect consumers).

The Deputy Administrator therefore concludes that the interpretation adopted in this final order is consistent with the words of the statute, its place in the overall drug enforcement legislative scheme and the problems Congress was attempting to address.

In adopting her limited interpretation of ''listed chemical'' under 971(c)(1), the ALJ cited three prior DEA cases in support of her position: Suspension of Shipment Cases,[4] 65 FR 51333 (2002); Yi Heng Enterprises Dev. Co., 64 FR 2234 (1999); and Neil Laboratories, Inc., 64 FR 30063 (1999). The Deputy Administrator finds these cases readily distinguishable, as they did not involve or discuss the question of chemical identity, which is at issue here. Instead, each of these cases dealt with other listed chemicals which were distributed in their original state and, unlike the PDK-bound imports, were not destined to be subjected to the introduction of fillers and coatings in order to transform them into over-the-counter drug products after importation and then placed into commerce.

While remanding, the Court of Appeal implicitly suggested that the then-Deputy Administrator's interpretation of 971(c)(1)'s ''listed chemical'' was permissible. However, in the majority's view it was arrived at under the erroneous impression that the statute ''plainly meant what the suspending orders assumed.'' PDK Labs, 362 F.3d at 794.

Disavowed of that view by the majority's guidance, based on the foregoing, the Deputy Administrator re-adopts the interpretation given by her predecessor to 971(c)(1)'s terms ''listed chemical'' and ''the chemical'' and holds they apply to regulated transactions involving listed chemicals regardless of imported or exported form, *i.e.,* bulk or finished products and that the provisions of 971 apply to finished products subsequently manufactured from bulk imported or exported listed chemicals.

The Deputy Administrator does not view this interpretation as managed by the ''plain language'' of the 971(c)(1). Instead, based on its experience and expertise, DEA concludes this is a reasonable interpretation which is consistent with the intent and language of the statute. It is also compatible with an in furtherance of the will of Congress in enacting the overall series of drug control laws serving to deter the illicit manufacturing, distribution and use of controlled substances and in furtherance of DEA's mission. Accordingly, should this final order be the subject of judicial scrutiny, it is requested that it be afforded appropriate deference. *See, Chevron* v. *NRDC, supra,* 467 U.S. at 865–66; PDK Labs, *supra,* 362 F.3d at 794.

The ALJ also disagreed with the Government's interpretation of 971(c), finding it would create a form of ''strick liability'' for the importers in this case. As discussed previously, although the suspension was directed against the importers, the party in interest in this proceeding is the manufacturer-customer of the importers. It is the conduct of that party, PDK, and its customers, and the fact that the product which it manufactured and distributed ended up in clandestine drug laboratories, that forms the basis of the Government's contention that the ephedrine ''may be diverted.''

The then-Deputy Administrator concluded in Mediplas, *supra,* 67 FR 41,256, published subsequent to the ALJ's recommendation in the instant case, that whether a regulated person foresaw or knew of diversion was not a determining factor as to whether the listed chemical ''may be diverted.'' While knowledge of a regulated person, or its party in interest customer, may be relevant in a totality of the circumstances analysis, the ultimate issue is whether the listed chemical being imported into the United States ''may be diverted'' and then, whether or not the Deputy Administrator should exercise her discretion to sustain the suspension of shipment.

The focus of the factual inquiry is the ultimate destination of the listed chemical, not the culpability of the regulated person. Indeed section 971(1), by its terms, makes no mention of a

[4] 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; Suspension of Shipments (collectively referred to as Suspension of Shipment Cases).

showing of intent, recklessness, negligence, knowledge, or any type of *mens rea*. Rather the plain language of the provision focuses solely upon whether the chemical ''may be diverted.'' Any contention that the ''may be diverted'' standard should be interpreted to contain a culpability element, cannot be squared with the plain language of that provision. *See American Tobacco C.* v. *Patterson,* 456 U.S. 63, 68 (1982) (''As in all cases involving statutory construction, our starting point must be the language employed by Congress and we assume that the legislative purpose is expressed by the ordinary meaning of the words used.'' (internal quotations omitted); *United States* v. *Green Drugs,* 905 F.2d 694,697–98 (3rd Cir. 1990) (holding that strict liability may be imposed for civil violations of the recordkeeping provisions of the CSA because ''[o]ur starting point is, of course, the text of the statute itself, which plainly shows an absence of the scienter requirement for civil violations of the recordkeeping provisions.'').[5]

While Mediplas was published after the ALJ issued her Opinion and Recommendation, the argument that an importer and, by logical extension, PDK as its party in interest, must have some degree of responsibility for the diversion, had previously been rejected by DEA ion a transshipment case. In Yi Heng Enterprises Dev. Co., *supra,* 64 FR 2,234, a transshipper of potassium permanganate through a U.S. port argued it had committed no violations in the past when it sold listed chemical to customers in Colombia. Even though the record demonstrated the transshipper's customers had committed numerous violations with listed chemicals purchased from the transshipper, that company contended that it had no control, and thus, should not be responsible for the transgressions of its downstream customers. Yi Heng unequivocally rejected this argument holding, ''[t]he prior conduct of [the transshipper's] customers * * * is clearly relevant in determining whether the shipments may be diverted.'' *Id.,* at 2,235.

To the extent the ALJ here concluded the Government's interpretation of ''may be diverted'' represents a ''radical shift in policy'' that must be accomplished through rulemaking, as opposed to adjudication, the Deputy Administer disagrees. The statute's language on this point and its meaning are sufficiently clear. DEA need not issue an array of regulations to anticipate every situation where a List I chemical may be diverted and the importer/exporter is entitled to an ''agency hearing on the record in accordance with subchapter 5 of Title 5.'' 21 U.S.C. 971(c)(2). The statute clearly envisions permitting the agency to proceed by adjudication.

Further, the instant suspension orders entail no new standards. They simply require a determination of specific facts. Similarly, the Government's position cannot be characterized as a ''radical departure.'' To the contrary, it is consistent with prior rulings, particularly Yi Heng and Mediplas.[6]

Applying the interpretations of 971(c)(1) discussed above and the totality of the circumstances test applied in Mediplas and the initial action on this matter, the Deputy Administrator now determines whether evidence exists to support the suspensions, based upon a finding that the List I chemicals may be diverted.

The Deputy Administrator finds DEA initiated a program intended to inform listed chemical registrants of situations when their listed chemicals products were discovered at illicit clandestine laboratory sites. According to DEA, a Warning Letter program was developed to assist registrants in identifying products that had been diverted and so they could decide appropriate remedial action.

On March 19, 1998, DEA issued a Warning Letter to PDK indicating that, from April 2, 1997, through December 20, 1997, PDK List I chemical products were found in 51 sites in Oklahoma, Missouri, Arkansas, Alabama, Kansas, California, Texas, Tennessee, Ohio, Florida, Iowa, Michigan, South Dakota, Arizona, Utah and Colorado, all in connection with the clandestine manufacture of controlled substances.

For investigative reasons, DEA did not resume sending any Warning Letters to PDK until February 15, 2000, when it issued a Warning Letter indicating that during 1998–99, PDK's ''Max Brand Pseudo 60's,'' ''Mini Tabs,'' ''Max Alert Pseudo,'' ''Mini Pseudo,'' ''Mini Two Way'', ''Mini Two Way Action'' and ''Mini Thins'' products were found in approximately 49 sites in eleven states, all in connection with the clandestine manufacture of controlled substances.

On February 15, 2000, DEA issued a Warning Letter to PDK indicating that 500 bottles of PDK's ''Max Brand Mini-Tabs'' product were found on June 25, 1999, in connection with the clandestine manufacture of controlled substances.

On February 17, 2000, DEA issued a Warning Letter to PDK indicating that 48 bottles of PDK ''Mini Pseudo'' product were found on October 26, 1999, in Dooly County, Georgia; that 1564 bottles of PDK ''Mini Pseudo'' product were found on March 24, 1999, in San Bernardino County, in California; that 8 bottles of PDK ''Mini Two Way Action'' product were found on March 23, 1999, in Detroit, Michigan; that 12,931 bottles of PDK ''Max Brand Pseudo 60's'' product were found on February 18, 1999, in Chatsworth, California; and that 40 bottles of PDK ''Mini Pseudo'' product were found on February 12, 1999, in Seattle, Washington, all in connection with the clandestine manufacture of controlled substances.

On February 28, 2000, DEA issued a Warning Letter to PDK indicating that 96 bottles of PDK ''Max Brand Pseudo 60's'' product and 144 bottles of PDK ''Two Way Max Brand'' product were found on January 27,2000, in McCrory, Arkansas; and that 13 bottles of PDK ''Max Brand Pseudo 60's'' product were found on February 14, 2000, in Dallas, Texas, both in connection with the clandestine manufacture of controlled substances.

On June 26, 2000, DEA issued a Warning Letter to PDK indicating that 1 bottle of PDK ''Max Brand Pseudo 60's'' product was found on December 22, 1999, in San Dimas, California; and that 143 bottles of PDK ''Max Brand Pseudo 60's'' product were found on January 6, 2000, in Las Vegas, Nevada, both in connection with the clandestine manufacture of controlled substances.

On June 6, 2000, DEA issued a Warning Letter to PDK indicating that 1 bottle of PDK ''Two Way Max Brand'' product and 2 bottles of PDK ''Max Brand Pseudo 60's'' product were found on January 6, 2000, in Sparta, Tennessee; that 4 bottles of PDK ''Max Brand Pseudo 60's'' product were found on May 11, 2000, in Lawrence, Kansas; and that 5 bottles of PDK ''Two Way Brand'' product were found on May 19, 2000, in Hamilton, Alabama, all in connection with the clandestine manufacture of controlled substances.

On June 8, 2000, DEA issued a Warning Letter to PDK indicating that 9 bottles of PDK ''Max Brand Pseudo 60's'' product were found on May 11, 2000, in Lawrence, Kansas; that 6 bottles of PDK ''Max Brand Pseudo 60's'' product were found on May 12, 2000, in Signal Mountain, Tennessee; that 144 bottles of PDK ''Max Brand

[5] In 1998, Congress amended the recordkeeping requirements of the CSA to include a negligence provision. *See* 21 U.S.C. 842(a)(5), (a)(10). Notably, however, Congress did not similarly amend section 971(c) to include such a provision.

[6] To the extent a future reviewer should disagree with the Deputy Administrator's reading of 971(c)(1)'s ''may be diverted'' language and determine it is ambiguous, the agency position should be given due deference under Chevron, *See, INS* v. *Anibal Aguirre,* 526 U.S. 415, 425 (1999).

Pseudo 60's'' product were found on May 31, 2000, in Auburn, Washington; and that 2 bottles of PDK ''Max Brand Pseudo 60's'' product were found on June 5, 2000, in Ozawkie, Kansas, all in connection with the clandestine manufacture of controlled substances.

On July 5, 2000, DEA issued a Warning Letter to PDK indicating that 1,871 bottles of PDK ''Max Brand Pseudo 60's'' product were found on April 12, 2000, in Temecula, California, in connection with the clandestine manufacture of controlled substances.

On July 7, 2000, DEA issued a Warning Letter to PDK indicating that 6 bottles of PDK ''Max Brand Pseudo 60's'' product were found on December 17, 1999, in Freeport, Florida; and that 1 empty case indicating a volume of 144 bottles of PDK ''Two Way Max Brand,'' and 78 bottles of PDK ''Max Brand Pseudo 60's'' product were found on April 14, 2000, in Sherman, Texas, all in connection with the clandestine manufacture of controlled substances.

On July 7, 2000, DEA issued a Warning Letter to PDK indicating that 672 bottles of PDK ''Max Brand Pseudo 60's'' product were found on February 29, 2000, in Hillsboro, Oregon; that 12 bottles of PDK ''Max Brand Pseudo 60's'' product were found on March 23, 2000, in Gales Creek, Oregon; and that 3 bottles of PDK ''Max Brand Pseudo 60's'' product were found on April 6, 2000, in Washington County, Oregon, all in connection with the clandestine manufacture of controlled substances.

On July 13, 2000, DEA issued a Warning Letter to PDK indicating that 157 bottles of PDK ''Max Brand Pseudo 60's'' product were found on July 7, 2000, in Plano, Texas, in connection with the clandestine manufacture of controlled substances.

On September 23, 2000, DEA issued a Warning Letter to PDK documenting that 24 bottles of PDK ''Max Brand Pseudo 60's'' product were found on June 21, 2000, in Las Vegas, Nevada; that 36 bottles of PDK ''Max Brand Pseudo 60's'' product were found on August 3, 2000, in Portland Oregon; that 217 bottles and 2,880 packets of PDK ''Max Brand Pseudo 60's'' product and 7 packets of PDK ''Pseudo 60's'' product were found on September 8, 2000, in Las Vegas, Nevada, all in connection with the clandestine manufacture of controlled substances.

On September 23, 2000, DEA issued a Warning Letter to PDK indicating that 72 bottles of PDK ''Max Brand Pseudo 60's'' product were found on April 25, 2000, in Copeville, Texas; that 2 bottles of PDK ''Two Way Max Brand'' product were found on May 2, 2000, in Charlotte, North Carolina; that 142 bottles of PDK ''Max Brand Pseudo 60's'' product were found on July 7, 2000, in Reno, Nevada; and that 341 bottles of PDK ''Max Brand Pseudo 60's'' product and 7 packets of PDK ''Pseudo 60's'' product were found on September 1, 2000, in Portland, Oregon, all in connection with the clandestine manufacture of controlled substances.

On September 25, 2000, DEA issued a Warning Letter to PDK indicating that approximately 400 bottles of PDK ''Mini-Pseudo'' product were found on September 7, 2000, in Fallbrook, California, in connection with the clandestine manufacture of controlled substances.

On October 24, 2000, DEA issued a Warning Letter to PDK indicating that 15 bottles of PDK ''Max Brand Pseudo 60's'' product were found on August 22, 2000, in Cedar Rapids, Iowa; and that 1,152 bottles of PDK ''Max Brand Pseudo 60's'' product were found on March 14, 2000, in Turlock, California, both in connection with the clandestine manufacture of controlled substances.

On October 27, 2000, DEA issued a Warning Letter to PDK indicating that 287 bottles of PDK ''Max Brand Pseudo 60's'' product were found on October 20, 2000, in Lake Havasu City, Arizona, in connection with the clandestine manufacture of controlled substances.

On November 9, 2000, DEA issued a Warning Letter to PDK indicating that 504 bottles and 35 boxes of PDK ''Max Brand Pseudo 60's'' product were found on October 12, 2000, in Portland, Oregon, in connection with the clandestine manufacture of controlled substances.

On November 13, 2000, DEA issued a Warning Letter to PDK indicating that 15 bottles of ''Mini Tabs Two Way,'' 5 packets of PDG ''Two Way Max Brand'' product and 480 packets of PDK ''Max Brand Pseudo 60's'' product were found on July 31, 2000, in Little Rock, Arkansas; and that approximately 1,700 bottles of PDK ''Max Brand Pseudo 60's'' product were found on July 26, 2000, in Lawrence, Kansas, all in connection with the clandestine manufacture of controlled substances.

On November 15, 2000, DEA issued a Warning Letter to PDK indicating that 528 packets of PDK ''Max Brand Pseudo 60's'' product were found on September 27, 2000, in South Jordan, Utah, in connection with the clandestine manufacture of controlled substances.

On December 18, 2000, DEA issued a Warning Letter to PDK indicating that 354 bottles of PDK ''Ephedrine Two Way'' product were found on August 12, 2000, in Yakima, Washington, in connection with the clandestine manufacture of controlled substances.

On December 28, 2000, DEA issued a Warning Letter to PDK indicating that 12 bottles of PDK ''Max Brand Pseudo 60's'' product were found on February 24, 2000, in Stevenson, Alabama; that 1 bottle of PDK ''Max Brand Psuedo 60's'' and 1 bottle of PDK ''Two Way Ephedrine Max Brand'' product were found on September 6, 2000, in Russellville, Alabama; and that 144 bottles of PDK ''Max Brand Pseudo 60's'' product were found on December 12, 2000, in Dallas, Texas, all in connection with the clandestine manufacture of controlled substances.

On January 23, 2001, DEA issued a Warning Letter to PDK indicating that 25 bottles of PDK ''Two Way Max Brand'' product were found on June 20, 2000, in Sicklerville, New Jersey; and that 369 bottles of PDK ''Two Way Max Brand'' product were found on December 6, 2000, in Carson City, Nevada, both in connection with the clandestine manufacture of controlled substances.

It is recognized that the above Warning Letters reflect that pseudoephedrine listed products were found at these clandestine laboratories and dump sites, along with PDK's ephedrine chemical products. However, DEA is aware that there is a close relationship between these two listed chemicals in the methamphetamine manufacturing process and PDK used the same or similar distribution chain to distribute both forms of listed chemical products. Based on agency experience, DEA knows that the same or similar methods of diversion are employed by clandestine methamphetamine manufacturers to obtain both pseudoephedrine and ephedrine listed chemical products and that a history of diversion of one product is probative as to the potential for diversion of the other. Thus, the Deputy Administrator concludes that the diversion of PDK's pseudoephedrine chemical products reflected in the Warning Letters is highly relevant to the potential for future diversion of its ephedrine chemical products.

The Government did not introduce evidence as to the quantity of other manufacturer's listed chemical products that have been found to be diverted, only the quantities and types of PDK's products which had been the subject of Warning Letters for the period at issue. It is also recognized that section 971(c)(1) requires an exercise of agency discretion, given that all ephedrine chemical products require the importation of the listed chemical into the United States at some point in their manufacturing and/or distribution chain. Thus, literally every shipment is

subject to a *theoretical* possibility that it ''may'' be diverted.

DEA recognizes that it and other law enforcement agencies are aware of and able to take action against only a small number of the total clandestine methamphetamine laboratories and dump sites in this country. Accordingly, the specific universe of PDK product diverted, *vis a vis*, all other manufacturers' products, is a number which cannot be established with specificity. However, the Deputy Administrator notes that at a March 1998 meeting between DEA and PDK, DEA personnel concluded that PDK's listed chemical products were being reported as the most prevalently found products at illicit settings in this country, *i.e.*, ''PDK products were number one in terms of being seized at methamphetamine labs.'' Tr. 1613.

Given the quantities and diverse locations of PDK listed chemical products discovered at illicit sites reflected in the Warning Letters, DEA is able to draw a reasonable inference regarding the likelihood that the instant shipments may be diverted and to exercise its discretion as to the need to prohibit their import.

In Mediplas, without having to undergo any attempt at a comparative statistical analysis, the Deputy Administrator found ''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 * * *.'' Mediplas, *supra*, 67 FR at 41262. In comparison, PDK's 22 Warning Letters detail diversion of thousands of bottles of its previously imported List I chemicals to approximately 140 illicit methamphetamine laboratory-related sites located in at least 18 states.

The fact that a company's product has been discovered in clandestine laboratories and dump sites has been a regular basis for DEA taking adverse action against manufacturers and distributors of List I chemical products, again without attempting statistical comparative analysis. *See* OTC Distribution, *supra*, 68 FR at 70544 (14 Warning Letters in 21 months a factor in revoking registration of List I chemical product distributor); Sinbad Distributing, *supra*, 67 FR at 10233 (registration as a distributor of listed chemical products denied in part because two potential suppliers of applicant had received 15 Warning Letters between them); CHM Suppliers, 67 FR 9985, (2002) (same).

In *Neil Laboratories, Inc.* v. *Ashcroft*, 217 F. Supp.2d 80 (D.D.C. 2002), DEA had issued an immediate suspension of a List I manufacturer's registration under 21 U.S.C. 824(d). The registrant challenged that action and the district court upheld the DEA order based, in part, on the fact that ''Neil Labs received approximately 30 warning letters from the DEA between February 4, 1999, and March 11, 2002, that identified various instances in which Neil Labs' product had been diverted to illicit uses.'' *Id.*, at 87.

The Deputy Administrator finds the record shows through testimony and documentary evidence that over a period of several years, PDK and DEA corresponded and met with the intention of resolving problems pertaining to the diversion of PDK's ephedrine and pseudoephedrine products. Evidence presented by PDK indicated it had taken steps to implement controls in its plant and distribution chain and during this period, DEA permitted certain listed chemical shipments, destined for PDK, to be imported. Nevertheless, as documented by the Warning Letters, PDK's products continued to appear at illicit settings in substantial amounts, despite remedial efforts undertaken or promised by the company. As the Court of Appeal observed in *ALRA Laboratories, Inc.* v. *DEA*, 54 F.3d 450 (7th Cir. 1995), ''An agency rationally may conclude that past performance is the best predictor of future performance.'' *Id.*, at 452.

As a collateral matter, it is noted that the individual responsible for implementing PDK's operating procedures for responding to DEA Warning Letters was Mr. Michael Lulkin. Beginning in 1990, Mr. Lulkin, an attorney, had served as PDK's outside counsel. In 1995, he was hired as in-home counsel and became PDK's Vice President of Legal Affairs and subsequently it's Director of Administrative Affairs. In 1998, Mr. Lulkin, along with PDK's then-President, Mr. Michael Krasnoff, was convicted in Federal court of four felony counts relating to securities fraud, money laundering and mail fraud. The mail fraud offenses involved PDK. Mr. Lulkin was subsequently disbarred from the practice of law in 1999.

PDK's Board of Directors and its current President, Mr. Reginald Spinello, who had worked for Mr. Krasnoff as PDK's Executive Vice President for Operations since 1991, allowed Mr. Krasnoff and Mr. Lulkin to remain associated with PDK. After resigning as President in 1998, Mr. Krasnoff continued to serve as a consultant to the company. Mr. Lulkin continues as an employee of PDK, where his duties include overseeing the company's regulatory compliance.

Neither of these personnel decisions, but particularly the retention of Mr. Lulkin as a key overseer of regulatory matters, despite his convictions for fraud and a felony against the company, generates confidence on the part of the Deputy Administrator that PDK is sufficiently committed to complying with the myriad of regulatory requirements designed to prevent diversion of listed chemicals.

In sum, the Deputy Administrator finds, based on the foregoing, that the bulk ephedrine which is the subject of the Suspension of Shipment Orders is a ''listed chemical'' that ''may be diverted'' and that the orders should be sustained.

As discussed earlier, the full court in *PDK Labs* agrees remand was necessary because the then-Deputy Administrator had also concluded PDK violated export notification requirements in connection with the sale and delivery of ephedrine products to Sun Labs of Canada. Because the evidence showed the product was actually delivered to the customer within the United States, the Court concluded the then-Deputy Administrator had failed to explain the agency's apparent divergence from its decision in *Alfred Khalily, Inc., supra* 65 FR 31,289 (1999). *See PDK labs, supra*, 362 F.3d at 798–99.

In *Khalily*, the then-Deputy Administrator agreed with the ALJ that the respondent company was not responsible for filing export documentation regarding its sale of a listed chemical, hydriotic acid, to a Mexican based company, R.J. Meyer. The key findings were that ''R.J. Meyers's purchase orders revealed that the shipments were either consigned to Jose Gutierrez, and sometimes Gus Pimental c/o Sky Harbor Delivery in Tucson, Arizona, or to Jose Gutierrez c/o Gus Pimental ata warehouse in Phoenix, Arizona'' and ''According to Respondent's invoices, Respondent sold the hydriotic acid to R.J. Meyer, but it was shipped to Jose Gutierrez at Sky Harbor Delivery. These shipments were 'FOB Destination,' which according to Mr. Khalily means that the shipper's responsibility ends when the product is delivered to the specified location.'' *Khalily, supra*, 64 FR at 31, 290.

The chemicals had been shipped to the Arizona warehouse and subsequently picked up by Mr. Gutierrez who, it turned out, was not a representative of R.J. Meyer. The chemicals were then loaded into a rental truck and disappeared. R.J. Meyer's personnel testified that the shipments never entered Mexico and DEA was

unable to determine their disposition after they left the Arizona warehouse.

The then-DEA Deputy Administrator concluded, ''While Respondent was selling above threshold quantities of hydriotic acid to a Mexican company, these sales were ''FOB Destination'' transactions and *therefore Respondent's responsibility* ended when the chemicals were delivered to the warehouse in Arizona. Respondent did not send or take the listed chemicals out of the United States, nor was it the 'principal party in interest' with the power and control for sending the chemicals out of the United States. Therefore, it was not responsible for filing any export documentation.'' Khalily, 64 FR at 31293 (emphasis added).

In the instant case, the then-Deputy Administrator concluded that ''[g]iven the circumstances of these sales, and especially given that PDK actually believed the product was destined for export, that PDK should have complied with DEA export regulations in effect at the time.'' 67 FR at 77808. He also concluded the ''record shows that PDK violated DEA export regulations on at least four occasions by failing to file the required notifications of its shipments to Sun Labs.'' 67 FR at 77809.

Notwithstanding Khalily, under the unique facts of this case the Deputy Administrator agrees that PDK should have filed export notifications with DEA.

The evidence shows that between 1994 and 1995, PDK sold Sun Labs of Canada at least four shipments of ephedrine and ephedrine hydrochloride, a listed chemical. During these proceedings, the parties disputed whether these shipments were ''exports,'' which required filing of a DEA Form 486 report within 15 days of the ''export,'' pursuant to 21 CFR 1313.21. That regulation provides, in relevant part, ''no person shall export or cause to be exported from the United States any [listed chemical] * * * until such time as the Administrator has been notified. Notification must be made not later than 15 days before the transaciton is to take place.'' 21 CFR 1313.21(a).

Neither PDK nor Sun Labs, nor their then-principals, were strangers. At the time, the President and owner of Sun Labs was Mr. Perry Krape, a former principal and a founder of PDK who, up until November of 2000, retained 8% ownership in PDK.

The ALJ noted in her findings that Mr. Krasnoff, discussed earlier as the subject of felony convictions involving the company, was PDK's President during this period. Mr. Krasnoff testified that these orders were delivered to Sun Labs at PDK's facility in Hauppauge, New York. He further testified it was PDK's belief that, after picking up the product, Mr. Krape's immediate intention was to transport it to his storage facilities in New York. Although there was no testimony that the ephedrine product was actually shipped to Canada, the Deputy Administrator finds it reasonable to infer that it was destined for Canada and to only remain in the United States temporarily.

The invoices indicated the customer was Sun Labs, located in Mississauga, Ontario, Canada. A DEA diversion investigator testified that ''the address on the invoices and the shipping labels, the shipping documents, indicated it was going to Ontario, Canada.'' Additionally, the investigator testified that each of the bills of lading for these transactions stated the ephedtine was being billed to and shipped to Sun Labs in Ontario, Canada.

While there were no shipping charges on the invoices and the ''Name of Carrier'' on the bills of lading listed either ''Pick-up'' or ''Perry Krape,'' the invoices, which were introduced into evidence, stated a ''Ship to'' address of ''Sun Labs, Inc., 300–2400 Dun Dun St West, Mississauga ON L5K2R8.'' The ''Bill to'' address on the invoices was the same foreign location. The bills of lading further identified the ''To Consignee'' as Sun Labs Inc. at its Mississauga, Ontario address.

Mr. Krasnoff also assumed Sun Lab's owner was going to distribute this product in Canada, as Mr. Krasnoff testified PDK had a ''no-compete'' agreement with Sun Labs in which Sun Labs agreed it would not sell ephedrine in PDK's territory, which included the entire United States. Further, Mr. Krasnoff testified in reference to these transactions, that he ''believe[d] that [Sun Labs] intention was to take the product to Canada at some point in time and that [Sun Labs] was putting together a distribution system in order to distribute that produce in Canada.'' Finally, Mr. Krasnoff states that Mr. Krape had said he ''was going to be the ephedrine king of Canada.'' [7]

For purposes of these export regulations, 21 CFR 1312.02, defines the term ''chemical export'' to cover more than just the physical sending or taking of the listed chemical out of the United States. Instead it provides ''The term '*chemical export*' means transferring ownership or control, *or* the sending of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the Unites States).'' 21 CFR 1313.02(a) (1995), now 21 CFR 1300.02(b)(5) (italics in original, emphasis added).

In Khalily, the shipment was consigned ''F.O.B'' to a buyer at an Arizona warehouse and the ALJ and then-Deputy Administrator were obviously focused on the implications of the ''F.O.B'' transfer *i.e.*, ''Respondent's responsibility ended when the chemicals were delivered to the warehouse in Arizona.'' Khalily, *supra*, 64 FR at 31,293. Further, there was no evidence that the listed chemicals were ever sent to Mexico. The facts here are distinguishable.

The invoices and bills of lading identify the listed chemical products as being purchased by and ''shipped to'' Sun Labs, a Canadian company at its foreign address in Ontario. While the bills of lading also indicated the product was going to be ''picked up'' at PDK's Hauppauge premises, even if the product was not being immediately transported across the border, ''ownership'' and ''control'' was knowingly transferred by PDK to a company located *outside* of the United States, thus falling within the definition of ''chemical export''—which ''no person'' (including PDK) ''shall export or cause to be exported from the United States * * * until such time as the Administrator has been notified.'' 21 CFR 1313.21(a).

While Mr. Krape apparently picked the listed chemicals up at PDK's New York location, the Deputy Administrator concludes PDK knew the listed chemicals were going to be physically taken outside the United States, albeit at an uncertain date, which the company never sought to ascertain and/or report. Where ownership and control was transferred to a foreign company, under the unique facts of this case, the Deputy Administrator concludes that export regulations required PDK to notify DEA of the transactions.

Compliance with regulatory requirements is relevant to the risk of diversion the listed chemicals will face as they progress through the chain of commerce from importation and/or exportation, manufacture and ultimate distribution through wholesalers and retailers. With regard to exports, DEA is aware that precursor chemicals can be brought into the United States from their countries of origin and then exported to other countries, where they are diverted to the manufacture of

[7] Although he is no longer with PDK, Mr. Krasnoff was also quoted as saying in May of 1996, ''it's none of my business if someone gets high off of this stuff,'' demonstrating an improper attitude for an officer of a DEA registrant and a cavalier approach toward complying with DEA regulations, including those pertaining to exports.

methamphetamine and other controlled substances and then subject to being smuggled back into the United States. *See e.g.,* Neil Laboratories, *supra,* 64 FR at 30,064 (exportation of pseudoephedrine from New Jersey to Mexico suspended because of risk of diversion). Further, the government's evidence showed that Sun Labs had a toll free 800 number and took orders from customers in the United States for List I chemical products, thereby returning them to this country. Additional, the Government offered testimony that DEA ''was beginning to see Canadian product showing up in large numbers in [clandestine] labs.'' Tr. at 753.

An exporter/transshipper's failure to comply with the notification requirements of 21 CFR 1313.31 has previously been cited as a ground for suspending shipments. *See e.g.,* Yi Heng Enterprises Dev. Co., *supra,* 64 FR at 2,235 (respondent transshipper concedes point and DEA holds ''it is undisputed that no advance notification of * * * shipments * * * was provided to DEA as required by the regulations and that this provides a basis for the suspension of these shipments.''); Suspension of Shipments, *supra,* 65 FR at 51,338 (''Finally, [the transhipper] failed to file advance notification of these shipments.'').

The Deputy Administrator recognizes that PDK's regulatory omissions are mitigated by the facts of their age and that the company's failure to file notifications did not involve the specific shipments at issue in the suspension orders. Nevertheless, PDK's non-compliance with regulatory requirements in these instances is considered relevant.[8]

The Orders to Suspend Shipments also alleged that in 1995, PDK made direct mail orders sales of its ephedrine chemical products to individuals who were later arrested and convicted of manufacturing and possessing methamphetamine with intent to distribute and admitted obtaining their precurser chemicals from PDK. Based on her view of the evidence, the ALJ declined to find that these sales were suspicious transactions which should have been reported by PDK pursuant to 21 CFR 1310.05(a)(1).

The evidence showed that David Chapin ordered and received over 12,000 tablets of ephedrine, 25 mg, during February 1995 and Jason Young received over 8,800 tablets of the same product between June and October of 1995. Based on his consultations with a pharmacist, a DEA diversion investigator deemed these sales to be excessive, given the individual therapeutic dosage units recommended in the Physician's Desk Reference and the United States Pharmacy Index for a one month period of time. Based on a recommended dosage of six tablets per day, the investigator testified that ''[e]very individual (purchase) on the mail order from 1995 was excessive.'' David Chapin was subsequently arrested for having an operational methamphetamine lab and stated that the PDK was the source of his ephedrine. He was subsequently convicted and sentence to 96 months in Federal prison.

However, based primarily upon Mr. Krasnoff's testimony, the ALJ concluded that PDK believed Chapin and Young were repackaging the single-entity ephedrine tablets purchased from PDK for resale, thus the quantities would not have appeared to be suspicious and need not have been reported to DEA. While the Deputy Administrator agrees there was no evidence introduced that PDK specifically knew of the buyers' illicit manufacturing, the evidence indicates a disturbing willingness on the part of PDK to turn a blind eye toward diversion of its product.

The ALJ specifically fond that Mr. Kranoff told DEA investigators in a May 1996 investigation concerning these sale, that he could care less who ordered what and how much. He also stated that ''it's none of my business if someone gets high off this stuff.'' Significantly, the ALJ found Mr. Krasnoff's sworn testimony at the hearing, in which he denied making these statements, to be incredible. The Deputy Administrator agrees that this witness was not credible and that his credibility is also diminished by his convictions of felony offenses involving moral turpitude.

When pressed on cross-examination as to his belief that ''smallest of distributors were repackaging or reselling,'' Mr. Krasnoff testified that:

> We got the sense that there was a network of distributors who distributed his product that we manufactured either in a *Tupperware-type setting* of [sic] door to door sales, and/or some of them distributing the product through the mail, ad hoc mail order companies.

Tr. 1993 (emphasis added).

The Deputy Administrator finds this testimony, suggesting that mail order recipients were emptying tablets out of a 1,000 count bottle and reselling them in a Tupperware setting or door to door to be incredible, particularly when considered in light of its self-serving nature, Mr. Kraasnoff's other untruths while testifying, and his fraud based felony convictions. Accordingly, the Deputy Administrator finds that the subject sales should have been reported as suspicious. Further, this evidence establishes that in 1995, PDK, sold ephedrine products directly to individuals who diverted them to illicit purposes.

However, it also noted these transactions occurred a number of years ago, Mr. Krasnoff's relationship with PDK has finally been severed, PDK ceased its mail order sales and the company has reported a series of suspicious sales to DEA on other occasions. Nevertheless, the Deputy Administrator finds that PDK's past attitude and its engaging in these transactions, along with its failure to report them as suspicious, are relevant as to whether the current suspensions should be sustained.[9]

At the hearing, DEA witnesses testified regarding traditional retail outlets and non-traditional retail outlets and the types of listed chemical products distributed to these outlets. The traditional market is characterized by a short distribution pattern to large chain grocery stores, large chain convenience stores, large chain drug stores, large discount retailers and large chain convenience stores. These products are packaged in blister packs and are 30 mg in strength. The non-traditional outlets are characterized by a very lengthy distribution chain of listed chemical products packaged in higher strength and in bottles of 60 or more dosage units. The higher strength products are those products usually found at the illicit methamphetamine production sites.

The Suspicious Orders Task Force also identified as suspicious, customers who resell large volumes of listed chemical products to the ''independent convenience store'' market. While PDK does not currently distribute List I chemical products directly to the public or to retail sales outlets, including convenience stores, witnesses indicated that through its distribution scheme, PDK is the largest supplier of generic List I chemical products to the convenience store market.

Since the hearing on this matter, a series of DEA final orders have addressed the distribution of listed

[8] For clarification should this final order be appealed, the Deputy Administrator finds that the evidence of diversion reflected in the series of Warning Letters provides a sufficient basis for sustaining the suspension orders, independent of the export notification infractions.

[9] However, again for clarification of future reviewers, notwithstanding the above findings, the Deputy Administrator finds that the evidence of diversion reflected in the series of Warning Letters provid3es a sufficient independent basis for concluding that the List I chemicals may be diverted and the suspension orders sustained.

chemical products through the gray market and in particular, through independent convenience stores. In Mediplas, my predecessor discounted the probative weight of the Government's ''anecdotal'' evidence ''without some form of further extrinsic evidence to support these arguments.'' Mediplas, *supra*, 67 FR at 41,264. In sustaining the shipments in the initial final order here, my predecessor noted the evidence in PDK's hearing was ''essentially identical'' to the evidence in Mediplas. Accordingly, he applied the same rule and declined to find that the Government's evidence of PDK's gray market distribution chain supported the suspension orders. *See, e.g.*, Indace/Malladi, *supra*, 67 FR at 77808.

In Branex, Incorporated, *supra*, 69 FR at 8696 while then-Acting Deputy Administrator, I approve use of the above Mediplas evidentiary standard:

> In deference to my predecessor's ruling in [Mediplas], a finding regarding convenience stores [as] conduits for the diversion of listed chemicals does not necessarily translate to a finding regarding the existence of the so-called 'traditional' versus 'non-traditional' markets for products containing ephedrine and pseudoephedrine. Rather, in Mediplas, the then-Deputy Administrator found 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 [Citation].' 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.

Branex, *supra*, 69 FR at 8693.

However, at the Branex hearing the Government did introduce substantial extrinsic evidence satisfying the Mediplas standard. In that regard, I held:

> 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 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. * * *
>
> [T]he Acting Deputy Administrator . . . 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 the pseudoephedrine products supplied by Respondents to its customers did not follow the normal channel of distribution of 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 casts doubt on the legitimacy of the Respondent's customers, and brings some context to the diversion of the respondent's listed chemical product.

Branex, *supra*, 69 FR at 8,693; *see e.g.*, Xtreme Enterprises, Inc, supra, 67 FR at 76,197 (denying registration as a listed chemical distributor after testimony by Mr. Robbin on graymarket and holding that applicant's positive factors were ''far outweighed'' by lack of experience and ''the fact that she intends to sell ephedrine almost exclusively in the gray market.''). *See also* Value Wholesale, 69 FR 58,548 (2004) (citing Xtreme Enterprises, Inc. and denying registration inpart on intent to distribute to grey market); K & Z Enterprises, Inc., 69 FR 51475 (2004) (same); William E. ''Bill'' Smith d/b/a B&B Wholesale, 69 FR 22559 (2004) (same); John E. McCrae d/b/a J & H Wholesale, 69 FR 51480 (2004) (same); SPA Dynamic Wholesalers, 68 FR 61466 (2003) (citing Robbin study and denying registration as distributor to grey market).

While DEA has concluded in the above series of cases that grey market establishments, such as convenience stores and gas stations, constitute sources for the diversion of listed chemical products and can form the basis for adverse action against registrants and potential registrants, the Government's evidence which formed the basis for those holdings was not presented at PDK's hearing. Thus, PDK has not had an opportunity to refute or contest that evidence and it is outside the record.

Accordingly, the Deputy Administrator will continue to apply the Mediplas evidentiary standard to the instant record and declines to find that the vidence concerning the gray market introduced in this specific case supports a factual finding that the listed chemicals which are the subject of the two suspension orders ''may be diverted.''[10]

In arriving at this decision, the Deputy Administrator has considered PDK's stature and business activities in the business community, its efforts at compliance, as well as the evidence available to DEA up to the time of the hearing. The Deputy Administrator finds that there was sufficient evidence at the time of the hearing to support DEA's contention that the chemicals may be diverted. ''As the Deputy Administrator has previously noted, [e]vidence of a violation of law is not necessary to demonstrate that suspensions were lawful.'' Mediplas, supra, 67 FR at 41,262 citing Suspension of Shipments, *supra*, 65 FR at 51337. Therefore, the Deputy Administrator concludes that the suspensions set forth in the January 25 and 26, 2001, Order to Suspend Shipments of ephedrine hydrochloride issued to Indace and Malladi were justified.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 971 and 28 CFR 0.100(b) and 0.104, hereby orders that the suspensions of the above described shipments, be, and hereby are, sustained, and that these proceedings are hereby concluded.

This final order is effective immediately.

Dated: November 9, 2004.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on August 19, 2004, ISP, Freetown Fine Chemicals, Inc., 238 South Main Street, Assonet, Massachusetts 02702, made application

[10] However, as noted earlier, for the limited purpose of interpreting the term ''listed chemical'' as it appears in section 971(c)(1) and the policy implications of the alternatives, the findings and conclusions contained in the above cited cases are considered relevant to DEA's application of the agency's current knowledge and expertise.