DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with the policy of the Department of Justice, notice is hereby given that a proposed consent decree in *United States* v. *Western Processing Co., et al.*, Civ. Nos. C83–252M and C89–214M, was lodged with the United States District Court for the Western District of Washington, on November 25, 2002. That action was brought against defendants pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) for payment of past response costs incurred, and future response costs to be incurred, by the United States and the State of Washington at the Western Processing Superfund Site in Kent, Washington. (The site is being cleaned up and most past costs have already been recovered pursuant to several prior settlements.) This decree requires Union Oil Company of California (d/b/a Unocal) (''Unocal'') and RSR Corporation (RSR) to pay: (1) $474,447.16 to the United States, which represents 95% of the remaining United States'' past response costs at this site incurred from January 1, 1997 through June 30, 1998 (including interest); (2) $100,000 to the State of Washington for its past response costs; and (3) 95% of all response costs incurred by the United States and the State at the site after June 30, 1998 (upon being billed for such costs).

Five minor generators of hazardous substance are paying RSR and Unocal a total of $450,000 to resolve their liability for past and future response costs at the site. Finally, the United States, on behalf of the Air Force, Army, Coast Guard, and Navy, will pay RSR and Unocal $118,000 to resolve any remaining liability it may have at the site.

The Department of Justice will receive comments relating to the proposed consent decree for a period of 30 days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530. All comments should refer to *United States* v. *Western Processing Co., et al.,* D.J. Ref. 90–7–1–233.

The proposed consent decree may be examined at the office of the United States Attorney for the Western District of Washington, 3600 Seafirst 5th Avenue Plaza, 800 5th Avenue, Seattle, Washington 98104; and at the Region X office of the Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101. A copy of the proposed consent decree may be obtained by mail from the Department of Justice Consent Decree Library, PO Box 7611, Washington, DC 20044–7611. In requesting a copy, please enclose a check in the amount of $14.75 (25 cents per page reproduction costs) payable to the Consent Decree Library. When requesting a copy, please refer to *United States* v. *Western Processing Co., et al.,* D.J. Ref. 90–7–1–233.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 02–31914 Filed 12–18–02; 8:45 am]

BILLING CODE 4410–15–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 Seegott, 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 on the appearance of products manufactured from imports of ephedrine and pseudoephedrine destined for PDK at illicit manufacturing sites.

On January 26, 2001, the then-Administrator of the Drug Enforcement Administration (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 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 on the appearance of products manufactured from prior imports of ephedrine and pseudoephedrine destined for PDK at illicit manufacturing sites.

On February 8, 2001, PDK requested a hearing in both matters, asserting standing as a Respondent pursuant to a ruling in *PDK Laboratories Inc.* v. *Reno, et al.,* 134 F.Supp.2d24 (D.D.C. 2001). DEA complied with the 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 recommending that both the suspensions be lifted, and the importers be allowed to complete the shipments. On April 25, 2002, the Government filed Exceptions to the ALJ's Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision. In response, on May 21, 2002, PDK filed PDK's Response to the Exceptions Filed by the Government. Subsequently, on June 5, 2002, the ALJ transmitted the record of these proceedings as her report to the Deputy Administrator for final action pursuant 5o 21 CFR 1313.57.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1313.57, hereby issues his final order regarding the Indace and Malladi suspensions of shipments based upon findings of fact and conclusions of law 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 hereafter noted, the Deputy Administrator rejects, in its entirely, the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

(hereinafter ''Recommendation''). Based on his 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 the 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.

A significant issue that must await future consideration by the Deputy Administrator is whether a party in PDK's position (*i.e.* a wholesale distributor/manufacturer who receives bulk listed chemicals from an importer) is in fact ''a regulated person to whom an order applies under paragraph (1)'' of 21 U.S.C. 971(c)(2) entitled to a hearing. In PDK *Laboratories Inc.* v. *Reno, et al.,* 134 F. Supp. 2d 24 (D.D.C. 2001), the court found, in reference to this processing, that PDK was ''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.'' The United States District Court for the District of Columbia has created a rule for this case; however, the Deputy Administrator declines at this time to adopt the rule as DEA policy.

On January 25 and 26, 2001, DEA issued the Orders to Suspend Shipment to Indace and Malladi that are the subject of this proceedings. The Orders asserted as a basis for the suspensions that the ephedrine to be imported may be diverted to the illicit production of a controlled substance. 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 hydrochoride 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).

The Deputy Administrator notes that the DEA Orders to Suspend Shipment recited that a DEA investigation revealed that products produced from prior imports of ephedrine and pseudoephedrine destined for PDK has appeared as 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 manufacturers and distributes over-the-counter drug products containing the listed chemicals pseudoephedrine and ephedrine, that these PDK 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 prodominantly encountered in larger clandestine methamphetamine laboratories.

In her Recommendation, the ALJ interpreted the terms ''listed chemical'' and the ''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 hydrochloride, as opposed to the products PDK manufactured from bulk ephedrine. The Deputy Administrator rejects this conclusion, and concurs with the following reasoning proposed by the Government.

The Government argues that the terms ''listed chemical'' as set forth in 971(a) and (c)(1) and ''regulated transaction'' in 971 (c)(1) must be construed in light of 21 U.S.C. 802(39)(A) and 21 U.S.C. 802(39)(A)(iv)(aa) regarding ''regulated transactions.'' While 802(39)(A)(iv) excludes FDA drug products generally from being included in ''regulated transactions,'' 802(39)(A)(iv)(I)(aa) explictly includes in the definition of ''regulated transaction'' any ''drug [that contains ephedrine or its salts, optical isomers, or salts of optical isomers[.]'' After 971 was made law in 1988, Congress in 1993 amended 21 U.S.C. 802(39)(A)(iv) to include, inter alia, ephedrine drug products under 802(39)(A)(iv)(I)(aa). Thus a ''regulated transaction'' includes any ephedrine drug product as a ''listed chemical.'' See also Section 401(f) of Pub. L. 104–237 set forth in the Historical and Statutory Notes to 21 U.S.C. 802.

The ALJ cites three prior DEA cases in support of her statutory interpretation of the term ''listed chemical:'' Suspension of Shipment Cases, 65 FR 51,333 (2002); Yi Heng Enters. Dev. Co., 64 Fed. Reg. 2,234 (1999); and Neil Laboratories, Inc. 64 FR 30,063 (1999). The Deputy Administrator finds these cases distinguishable in that none of the cases involve or discuss the same issue of chemical identity addressed in this case.

The Deputy Administrator finds additional support for the Government's position in United States v. Abdul Daas, 198 F.3d 1167, 1175 (9th Cir. 1999), cert. denied, 531 U.S. 999 (2002). The court in Daas found that the term ''listed chemical'' as used in 21 U.S.C. 841(d)(2) (now 841(c)(2)) and defined at 21 U.S.C. 802 (34) included finished List I chemical products that contain other ingredients. The Daas court stated: ''The chemical matrix in which ephedrine and pseudoephedrine are contained is irrelevant because they do not disappear, become different chemicals, or become useless when combined with other substances to make [finished products]. For the purposes of § 841(d)(2), the other ingredients * * * function solely as a carrier medium or packaging material facilitating distribution of the listed chemical.'' Id. at 1175. The court concluded that ''the plain meaning of 'listed chemical' encompasses the ephedrine and pseudoephedrine contained in [finished products].'' Id. The Deputy Administrator finds this analysis equally applicable to the instant case.

The Deputy Administrator has also considered the legislative history of the Domestic Chemical Diversion Control Act of 1993 (DCDCA), Public Law 103–200, § 9, 107 Stat. 2333 (1993). The then-acting DEA Administrator made a report to the House Committee clearly indicating that this legislation was intended, in part, to close the ''loophole'' for those who divert ephedrine drug products. H.R. Rep. 103–3791 at 5, 8 (1993), reprinted in U.S.C.C.A.N. 2983, 2986 (1993).

Accordingly, the ALJ's interpretation of ''listed chemical'' and ''the chemical,'' as those terms appear in 971(a) and (c), is hereby rejected. The Deputy Administrator finds that 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 or finished products. The Deputy Administrator further concludes the provisions of 971 apply to finished products subsequently manufactured from bulk imported list chemicals.

The ALJ also disagreed with the Government's interpretation of 971(c), finding that it would create a form of ''strict liability'' for the importers in this case. As mentioned previously, although the suspension was directed against the importers, the party in interest in this proceeding is the manufacturer-customer of the importer. 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 imported ''may be diverted.'' The Deputy Administrator concluded in the case of Mediplas Innovations, 67 FR 41256 (2002), 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 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.'' The focus of the inquiry is the ultimate destination of the listed chemical, not the culpability of the regulated person.

The Deputy Administrator concluded in Mediplas that the test for whether § 971(c) suspension orders are justified is ''whether the totality of the circumstances provides grounds to believe that the suspended chemical shipments may be diverted.'' Id. at 41262. In the instant case, the Deputy Administrator concludes that the totality of the circumstances supports the conclusion that the listed chemicals in the suspended chemical shipments may be diverted.

The DEA Orders to Suspend Shipment list various facts in support of the suspensions. The Orders to Suspend Shipment refer to four occasions during 1994–95, when PDK apparently shipped 25 mg. ephedrine tablets to a mail order distributor in Ontario, Canada without filing an export notification with DEA as required by 21 U.S.C. 971(a). In 1995, PDK made multiple shipments of ephedrine in response to mail order requests by individuals. In periods ranging from one to nine months, these individuals purchased 14,000 to 32,000 tablets of ephedrine. The Orders further allege that PDK failed to make reports of transactions of extraordinary quantities of listed chemicals, and that three individuals who purchased thousands of dosage units of ephedrine from PDK by mail order were convicted of methamphetamine manufacturing offenses. The Orders also state that in 1997, PDK was issued a Warning Letter by DEA stating that approximately 51 methamphetamine laboratory-related sites were found to contain evidence of PDK products, and that in 1998–99, approximately 49 methamphetamine laboratory-related sites were found to contain evidence of PDK products. Finally, the orders stated that from February 2000 through January 2001, DEA issued 22 Warning Letters notifying PDK that its products had been found at over 40 different clandestine methamphetamine laboratory-related sites in several states.

These recitations were relied upon by the Government to support its finding that pursuant to 971(c) the ephedrine proposed to be imported may be diverted for the illicit production of a controlled substance. The Government contends that evidence supporting these recitations would be sufficient to show that the listed chemicals may be diverted.

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 ephedrine or pseudoephedrine. 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 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), Public Law 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. Those listed chemicals contained in drug products were exempted at that time.

In response to these controls, illicit methamphetamine laboratories began to switch to tableted ''single entity'' ephedrine as a raw material. The Domestic Chemical Diversion Control Act of 1993 (DCDCA), Public Law 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), Public Law 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.

The Deputy Administrator finds that evidence was presented at the hearing to include certain data gathered from law enforcement sources and analyzed by DEA. This information demonstrated that seizures involving illicit methamphetamine laboratories have been increasing in recent years. For example, DEA methamphetamine laboratory-related seizures grew from 263 to more than 2,000 over the period from 1994 to 1999.

An additional number of state and local law enforcement methamphetamine-related seizures were reported in 1999.

The Deputy administrator finds that the record shows that DEA initiated a Warning Letter program intended to inform listed chemical registrants when their listed chemical products are discovered at illicit clandestine laboratory-related sites. According to DEA, this program was developed to assist DEA registrants to: (1) Identify products that had been diverted, and (2) allow registrants to decide upon appropriate remedial action. The record indicates and the Deputy Administrator finds that the Government presented evidence to show that 22 Warning Letters were issued to PDK advising it of the diversion of its listed chemical products. The first Warning Letter, sent to PDK in march 1998, documented 51 occasions in which PDK ephedrine and pseudoephedrine were found at various sites related to the illicit manufacture of methamphetamine. It appears that for investigative reasons, DEA did not resume sending Warning Letters to PDK until February 2000.

The Deputy Administrator finds that on February 15, 2000, DEA sent PDK a Warning Letter, which notified PDK that

throughout 1999 PDK's ephedrine and pseudoephedrine products had been discovered in sites related to the illicit manufacture of methamphetamine in eleven states. Thereafter, DEA sent PDK twenty more Warning Letters between February 2000 and January 2001. The Warning Letters notified PDK of the location of the illicit sites where PDK's ephedrine and pseudoephedrine products were discovered. The Warning Letters documented that PDK products were discovered in 18 states, including California and Missouri, where PDK had previously agreed with DEA not to sell listed chemical products. These Warning Letters documented that the range of 60 count bottles found at these various sites was from just a few bottles to about 14,000 bottles.

In Mediplas, 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, 67 FR at 41262. In this case, PDK received 22 Warning Letters documenting the diversion of thousands of bottles of its List I chemical products to approximately 140 illicit methamphetamine laboratory-related sites in at least 18 states. As in mediplas, the Deputy Administrator concludes that the Warning Letters issued to PDK provide substantial evidence documenting the diversion of thousands of bottles of its List I chemical products to ''the clandestine manufacture of a controlled substance.'' Mediplas, 67 FR at 41262; 21 U.S.C. 971(c)(1).

The Deputy Administrator finds that 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 the problem regarding the diversion of PDK's ephedrine and pseudoephedrine products. Evidence presented by PDK indicated that it had taken steps to implement controls in its plant and distribution chain. During this period, DEA permitted certain listed chemical shipments, destined for PDK, to be imported. However, testimony shows that DEA personnel and PDK were not in agreement as to the level of success at controlling diversion of the PDK products. The Deputy Administrator concludes that the continued discovery of PDK's products in illicit settings, as documented by the Warning Letters, shows that diversion continues to occur.

The Deputy Administrator further finds that evidence was presented at the hearing that PDK, between 1994 and 1995, sold to Sun Labs of Canada at least four shipments of ephidrine. The president and owner of Sun Labs at the time was Perry Krape, former owner of PDK. The parties disputed whether these shipments were exports, which would then have required reporting to DEA on a DEA Form 486 within 15 days of the export pursuant to 21 CFR 1313.21(a). The ALJ noted in her findings of fact that Mr. Krasnoff of PDK credibly testified that these orders were delivered to New York, and further noted that Mr. Krasnoff assumed that Sun Labs's owner was going to distribute this product in Canada. The ALJ also noted that Mr. Krasnoff had a ''no-complete'' agreement with Sun Labs in which Sun Labs agreed that it would not sell ephidrine in PDK's territory, which included the entire United States. Although the ALJ noted that there was no testimony to demonstrate that the ephidrine actually was shipped to Canada, the Deputy Administrator finds that it is a reasonable inference that the ephidrine was destined for Canada, and that the ephidrine was not destined to remain in the United States in storage areas indefinitely. In fact, 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 product in Canada.'' The Deputy Administrator finds, given the circumstances of these sales, and especially given PDK actually believed the product was designed for export. that PDK should have complied with DEA export regulations in effect at the time. The Deputy Administrator therefore concluded PDK violated 21 CFR 1313.21 by failing to file export notifications for each of the four shipments at issue, regardless of whether the ephidrine actually left the United States.

The Deputy Administrator notes that at that 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 Government alleges that the traditional market is characterized by a short distribution pattern to large chain grocery 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. DEA alleges the non-traditional outlets are characterized by a very lengthy distribution chain of listed chemical products and that these products are sold by gas stations, liquor stores, hair salons, ''head'' shops, and video stores. Allegedly, the non-traditional market packaging differs from the traditional market because non-traditional retail outlets sell pseudoephedrine in 60 mg. strength in bottles of 60 or more dosage units. The higher strength products are those products usually found at the illicit methamphetamine sites.

The ALJ noted that the Suspicious Orders Task Force identified certain ''suspicious orders'' identification criteria. This criteria included certain retail stores identified as ''non-traditional'' outlets for over-the-counter regulated products, for example, head shops, drug paraphernalia stores, liquor stores, record stores, and video shops. The Task Force Report did not identify convenience stores as ''nontraditional'' outlets. The Task Force Report criteria did identify as suspicious customers who resell large volumes into the ''independent convenience store'' market. The Deputy Administrator notes the record shows PDK does not distribute List I chemical products directly to customers, nor to any retail sales outlets, including convenience stores.

In Mediplas the Government also presented testimony concerning ''traditional'' versus ''non-traditional'' markets for List I chemical products. 67 FR at 41264. The Deputy Administrator found in that cast the ''the probative weight of this [anecdotal] evidence is minimal without some form of further extrinsic evidence to support these arguments.'' The Deputy Administrator adopts this finding in the present case, as the Government here relied upon essentially identical evidence as in Mediplas.

The Deputy Administrator has also considered the Government's arguments that PDK in 1995 and 1996 engaged in the mail order sale of excessive quantities of 25 mg. ephedrine products to consumers. A DEA Diversion Investigator testified that in his opinion, such sales to individuals, involving 14,000 to 32,000 tablets over periods ranging from one to nine months, were excessive in light of the levels of maximum therapeutic dosing. In addition, the record shows several individual retail customers received amounts of 12,000 dosage units or more per month. The record also shows that two of these customers were subsequently convicted of criminal felonies relating to the manufacture or distribution of methamphetamine and a third was arrested. The Government argues that PDK should have submitted reports to DEA concerning the transactions with these individuals

because such sales allegedly ''clearly'' excessive and should have been reported pursuant to 21 CFR 1310.05(a)(1).

The Deputy Administrator disagrees, and concerns instead with the position of the ALJ, who found DEA failed to prove by a preponderance of the evidence that PDK violated the excessive sales reporting requirements. The Deputy Administrator concurs with her finding that the record contains insufficient evidence to support the conclusion that the sales to these individuals constituted excessive quantities since the Government failed to rebut PDK's evidence that it reasonably believed the products were intended for repackaging and resale, and not for personal consumption by the purchasing individuals.

Further, despite the subsequent Federal arrest and conviction of two of these individuals for operating methamphetamine laboratories, the Deputy Administrator concurs with the ALJ's finding that there is no evidence in the record showing that PDK was aware if any illicit activity by these individuals at the time of the sales. The Deputy Administrator further concurs with the ALJ's finding evidence in the record demonstrating PDK's willingness to file suspicious transaction reports in cases where PDK had a factual basis for doing so.

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 DEA 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 41264. The fact that PDK products containing ephedrine and pseudolephedrine have repeatedly been 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.

In arriving at this decision, the Deputy Administrator has considered PDK's stature and 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. Mediplas, 67 FR at 41260–41261. As the Deputy Administrator has previously noted, ''[e]vidence of a violation of law is not necessary to demonstrate that the suspensions were lawful.'' Mediplas, at 67 FR at 41262, citing Suspension of Shipments, 65 FR at 51337. 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.

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) 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: December 13, 2002.

John B. Brown, III,

Deputy Administrator.

[FR Doc. 02–31949 Filed 12–18–02; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA # 237E]

Controlled Substances: Established Initial Aggregate Production Quotas for 2003

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2003.

SUMMARY: This notice establishes initial 2003 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

EFFECTIVE DATE: December 19, 2002.

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by Section 0.100 of Title 28 of the Code of Federal Regulations. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to Section 0.104 of Title 28 of the Code of Federal Regulations.

The 2003 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2003 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. 826(a) and 21 CFR 1303.11). These quotas do not include imports of controlled substances for use in industrial processes.

On November 1, 2002, a notice of the proposed initial 2003 aggregate production quotas for certain controlled substances in Schedules I and II was published in the **Federal Register** (67 FR 66663). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before November 22, 2002.

Ten companies commented on a total of twenty Schedules I and II controlled substances within the published comment period. The companies commented that the proposed aggregate production quotas for amobarbital, amphetamine, codeine (for sale), codeine (for conversion), dextropropoxyphene, dihydrocodeine, fentanyl, glutethimide, hydrocodone (for sale), hydromorphone, methadone (for sale), methadone intermediate, methamphetamine (for conversion), methamphetamine (for sale), morphine (for conversion), noroxymorphone (for sale), opium, oxycodone (for sale), sufentanil and thebaine were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks. One company commented that the proposed aggregate production quota for methamphetamine (for sale) was adequate to provide for the estimated medical needs of the United States.

DEA has taken into consideration the above comments along with the relevant 2002 manufacturing quotas, current 2002 sales and inventories, 2003 export requirements and research and product development requirements, and