

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 in part 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 evidence 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.

[FR Doc. 04-25695 Filed 11-19-04; 8:45 am]

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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.

by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed:

Drug	Schedule
2, 5-Dimethoxyamphetamine (7396)	I
Amphetamine (1100)	II
Phenylacetone (8501)	II

The company plans to manufacture phenylacetone to be used in the manufacture of the amphetamine. The bulk 2, 5-dimethoxyamphetamine will be used for conversion into non-controlled substances.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative, Office of Liaison and Policy (ODLR) and must be filed no later than January 21, 2005.

Dated: November 8, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 04-25767 Filed 11-19-04; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a registration under 21 U.S.C. 952(a)(2)(B) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on August 20, 2004, ISP Freetown Fine Chemicals, 238 South Main Street, Assonet, Massachusetts 02702, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of Phenylacetone (8501), a

basic class of controlled substance listed in Schedule II.

The company plans to import Phenylacetone to manufacture amphetamine.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections or requests for hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative, Office of Liaison and Policy (ODLR) and must be filed no later than December 22, 2004.

This procedure is to be conducted simultaneously with, and independent, of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745-46), all applicants for registration to import a basic class of any controlled substances in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: November 8, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 04-25768 Filed 11-19-04; 8:45 am]

BILLING CODE 4410-09-P

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 September 28, 2004, Orasure Technologies, Inc., Lehigh University, Seesley G. Mudd-Building 6, Bethlehem, Pennsylvania 18015, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk

manufacturer of the basic classes of controlled substances listed:

Drug	Schedule
Alphamethadol (9605)	I
Benzoylcgonine (9180)	II
Morphine (9300)	II

The company plans to manufacture the listed controlled substances in bulk to manufacture other controlled substances.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA **Federal Register** Representative, Office of Liaison and Policy (ODLR) and must be filed no later than January 21, 2005.

Dated: November 8, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 04-25769 Filed 11-19-04; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Employment and Training Administration

Trade Adjustment Assistance Program: Training and Employment Guidance Letter Interpreting Federal Law; Correction

AGENCY: Employment and Training Administration, Labor.

ACTION: Correction.

SUMMARY: In notice document 04-22919 beginning on page 60903 in the issue of Wednesday, October 13, 2004, make the following correction:

On page 60903, the heading to the document was omitted and should be added to read: Employment and Training Advisory System, U.S. Department of Labor, Washington, DC 20210.

Classification: TAA.

Correspondence Symbol: ONR.

Date: November 6, 2003.