

(3) Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) Any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) Such other factors as are relevant to and consistent with the public health and safety.

*Id.* "These factors are considered in the disjunctive." *Joy's Ideas*, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether an application for registration should be denied. *See, e.g., David M. Starr*, 71 FR 39367 (2006); *Energy Outlet*, 64 FR 14269 (1999).

I acknowledge that Respondent maintains effective controls against diversion. I also recognize that there is no evidence that Respondent, or any of its officers, has been convicted of a criminal offense under Federal or State laws related to controlled substances or chemicals. Applying factor two, however, I conclude that Respondent's application must be denied because of its lengthy non-compliance with the registration requirements. *See* 21 U.S.C. 823(h)(2).

The investigative file establishes that Respondent imported and distributed List I chemical products containing both pseudoephedrine and PPA for a period lasting over ten years. In the Methamphetamine Control Act of 1996, Pub. L. 104-237, § 401, 110 Stat. 3099, 3106-07-3113, Congress removed an "exemption from regulation as List I chemicals which had applied to pseudoephedrine" and PPA. Implementation of the Comprehensive Methamphetamine Control Act of 1996, 67 FR 14853 (2002). "This action [made] persons who distribute the products subject to the registration requirement," and also rendered "importations" of the products "subject to the existing chemical controls relating to regulated transactions" except for in certain limited circumstances. *Id.*

In the notice of proposed rulemaking implementing the Act, DEA clearly explained that "importers, exporters, and distributors (other than retail distributors) of pseudoephedrine and [PPA] drug products (including ordinary over-the-counter pseudoephedrine and [PPA] products) became subject to the registration requirement of the [Act] on October 3, 1997." Implementation of the Comprehensive Methamphetamine Control Act of 1996, 62 FR 52294, 52298 (proposed Oct. 7, 1997). DEA further explained that "[a]ny person who engages in such activities and is not subject to an existing or proposed

exemption from the registration requirement should submit an application for registration at the earliest possible time, to ensure that they may continue to distribute these products pending issuance of their registration." *Id.* Finally, DEA stated that it was "providing a temporary exemption from the registration requirement for persons who submit[ted] their applications on or before December 3, 1997." *Id.*

In accordance with the Comprehensive Methamphetamine Act, and DEA's interpretation of it, Respondent was required to submit an application for the necessary registrations no later than December 3, 1997. Thus, at the time Respondent finally notified DEA of its non-compliance, it had been unlawfully importing and distributing pseudoephedrine (and possibly PPA) for more than six years. *See* 21 U.S.C. 843(a) (9) and 957(a).<sup>2</sup>

I do not find persuasive Respondent's explanation that it was unaware that pseudoephedrine had been regulated as a list I chemical. While I appreciate that Respondent voluntarily disclosed its misconduct to DEA and ceased all distribution of its pseudoephedrine products, the duration and scope of Respondent's misconduct cannot be overlooked. Registration is one of the essential features of the CSA; Respondent's failure to register to import and distribute List I chemicals simply cannot be characterized as a technical violation of the Act.

It is well settled that "ignorance of the law or a mistake of law is no defense." *Cheek v. United States*, 498 U.S. 192, 199 (1991). Moreover, the principle "applies whether the law be a statute or a duly promulgated and published regulation." *United States v. International Minerals & Chemical Corp.*, 402 U.S. 558, 563 (1971). Respondent's ignorance of Federal law and regulations is especially troubling because it engages in the highly regulated industry of manufacturing, importing and distributing pharmaceuticals. There is simply no excuse for Respondent's failure to be on top of changes in Federal law and regulations that affect its business.

I therefore conclude that Respondent's lengthy failure of non-

<sup>2</sup> It also appears that Respondent failed to file DEA Form 486s to report its imports of pseudoephedrine. *See* 21 CFR 1313.12. However, the investigative file does not contain any documents such as bills of lading establishing that Respondent exceeded the one kilogram threshold which triggers the reporting obligation with respect to any particular importation. *See id.* 1310.04. Accordingly, I base this final order only on Respondent's failure to register.

compliance with the registration requirements demonstrates that granting its application would be inconsistent with the public interest. Furthermore, because of the seriousness and duration of these violations, I deem them dispositive of the ultimate issue and need not make findings on the remaining factors. *See Hoxie v. DEA*, 419 F.3d 477, 482 (2005); *Morall v. DEA*, 412 F.3d 165, 173 (2005).

#### Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. § 823(h), and 28 CFR 0.100(b) & 0.104, I hereby order that the previously submitted application of Sato Pharmaceutical, Inc., for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is, denied. This order is effective October 2, 2006.

Dated: August 22, 2006.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. E6-14522 Filed 8-31-06; 8:45 am]

BILLING CODE 4410-09-P

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## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### Advisory Council on Employee Welfare and Pension Benefit Plans; Working Group on Health Information Technology; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the Working Group assigned by the Advisory Council on Employee Welfare and Pension Benefit Plans to study the issue of Health Information Technology will hold an open public meeting on September 22, 2006.

The session will take place in Room S 4215 A-C, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The purpose of the open meeting, which will run from 8:30 a.m. to approximately 4:30 p.m., with a one hour break for lunch, is for Working Group members to hear testimony from invited witnesses. The Working Group will study what is necessary in order to encourage the widespread adoption of health information technology using common standards and how the Federal government can work with the private sector and industry to accomplish this.

Organizations or members of the public wishing to submit a written statement pertaining to the topic may do

so by submitting 25 copies on or before September 13, 2006 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N-5623, 200 Constitution Avenue, NW., Washington, DC 20210. Statements also may be submitted electronically to [good.larry@dol.gov](mailto:good.larry@dol.gov). Statements received on or before September 13, 2006 will be included in the record of the meeting. Individuals or representatives of organizations wishing to address the Working Group should forward their requests to the Executive Secretary or telephone (202) 693-8668. Oral presentations will be limited to 20 minutes, time permitting, but an extended statement may be submitted for the record. Individuals with disabilities, who need special accommodations, should contact Larry Good by September 13, 2006 at the address indicated.

Signed at Washington, DC this 28th day of August, 2006.

**Ann L. Combs,**

*Assistant Secretary, Employee Benefits Security Administration.*

[FR Doc. E6-14570 Filed 8-31-06; 8:45 am]

**BILLING CODE 4510-29-P**

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## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### Advisory Council on Employee Welfare and Pension Benefit Plans; 135th Full Council Meeting; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 135th open meeting of the full Advisory Council on Employee Welfare and Pension Benefit Plans will be held on September 20, 2006.

The session will take place in Room S 4215 A-C, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The purpose of the open meeting, which will run from 4 p.m. to approximately 5 p.m., is for members to be updated on activities of the Employee Benefits Security Administration and for chairs of this year's Working Groups to provide progress reports on their individual study topics.

Organizations or members of the public wishing to submit a written statement may do so by submitting 25 copies on or before September 13, 2006 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N-5623, 200 Constitution Avenue, NW., Washington, DC 20210. Statements also may be

submitted electronically to [good.larry@dol.gov](mailto:good.larry@dol.gov). Statements received on or before September 13, 2006 will be included in the record of the meeting. Individuals or representatives of organizations wishing to address the Advisory Council should forward their requests to the Executive Secretary or telephone (202) 693-8668. Oral presentations will be limited to 10 minutes, time permitting, but an extended statement may be submitted for the record. Individuals with disabilities who need special accommodations should contact Larry Good by September 13 at the address indicated.

Signed at Washington, DC this 28th day of August, 2006.

**Ann L. Combs,**

*Assistant Secretary, Employee Benefits Security Administration.*

[FR Doc. E6-14571 Filed 8-31-06; 8:45 am]

**BILLING CODE 4510-29-P**

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## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### Advisory Council on Employee Welfare and Pension Benefit Plans; Working Group on Plan Asset Rules, Exemptions, and Cross Trading; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the Working Group assigned by the Advisory Council on Employee Welfare and Pension Benefit Plans to study the issue of Plan Asset Rules, Exemptions, and Cross Trading will hold an open public meeting on September 20, 2006.

The session will take place in Room S 4215 A-C, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The purpose of the open meeting, which will run from 9 a.m. to approximately 4 p.m., with a one hour break for lunch, is for Working Group members to hear testimony from invited witnesses. The Working Group will study (1) the current applicability of the 1987 plan asset regulation, to determine whether the regulation should be modified or whether other DOL action is appropriate to clarify the existing regulation, and (2) cross trading, to determine whether the DOL should issue broader exemptive relief for cross-trading.

Organizations or members of the public wishing to submit a written statement pertaining to the topic may do so by submitting 25 copies on or before

September 13, 2006 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N-5623, 200 Constitution Avenue, NW., Washington, DC 20210. Statements also may be submitted electronically to [good.larry@dol.gov](mailto:good.larry@dol.gov). Statements received on or before September 13, 2006 will be included in the record of the meeting. Individuals or representatives of organizations wishing to address the Working Group should forward their requests to the Executive Secretary or telephone (202) 693-8668. Oral presentations will be limited to 20 minutes, time permitting, but an extended statement may be submitted for the record. Individuals with disabilities, who need special accommodations, should contact Larry Good by September 13, 2006 at the address indicated.

Signed at Washington, DC this 28th day of August, 2006.

**Ann L. Combs,**

*Assistant Secretary, Employee Benefits Security Administration.*

[FR Doc. E6-14576 Filed 8-31-06; 8:45 am]

**BILLING CODE 4510-29-P**

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## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### Advisory Council on Employee Welfare and Pension Benefit Plans; Working Group on a Prudent Investment Process; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the Working Group assigned by the Advisory Council on Employee Welfare and Pension Benefit Plans to study the issue of a Prudent Investment Process will hold an open public meeting on September 21, 2006.

The session will take place in Room S 4215 A-C, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The purpose of the open meeting, which will run from 9 a.m. to approximately 5 p.m., with a one hour break for lunch, is for Working Group members to hear testimony from invited witnesses. The Working Group will study selected issues regarding the prudent investment process for both defined benefit plans and participant directed defined contribution plans. The Working Group will focus on plan asset valuations, soft dollars, and self-directed account plans under ERISA Section 404(c).

Organizations or members of the public wishing to submit a written