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. E6–14524 Filed 8–31–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sato Pharmaceutical, Inc.; Denial of Application

On August 5, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Sato Pharmaceutical, Inc., (Respondent) of Torrance, California. The Show Cause Order proposed to deny Respondent's pending application for registration as a non-retail distributor of List I chemicals on the ground that Respondent's registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(h); Show Cause Order at 1.

The Show Cause Order specifically alleged that Respondent sells dietary supplements and Asian healthcare products to convenience stores and small markets. *See* Show Cause Order at 2. The Show Cause Order alleged that Respondent had been illegally importing from Taiwan and Japan pseudoephedrine 60 mg. products that were sold under the ''Stona'' brand. *See id.* The Show Cause Order further alleged that Respondent had been engaged in this activity for over ten years. *See id.* Finally, the Show Cause order alleged that Respondent had sold these products to distributors who also lacked a DEA registration. *See id.* The Show Cause Order further advised Respondent of its right to a hearing. *Id.*

The Show Cause Order was served by certified mail. Respondent, through its counsel, initially requested a hearing; the matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. Several days later, however, Respondent withdrew its request for a hearing and the ALJ terminated the proceeding. Thereafter, the investigative file was forwarded to me for final agency action. Because Respondent has expressly waived its right to a hearing, I hereby enter this final order based on relevant material in the investigative file and make the following findings.

Findings

Pseudoephedrine is a List I chemical that has a lawful therapeutic use. It is, however, easily extracted from over-the-counter products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. *See* 21 U.S.C. 802(34); 21 CFR 1308.12(d). As noted in numerous prior DEA orders, ''methamphetamine is an extremely potent central nervous system stimulant.'' *David M. Starr,* 71 FR 39637 (2006). Methamphetamine abuse has destroyed lives and families, ravaged communities, and created serious environmental harms.

Respondent is a United States subsidiary of a Japanese pharmaceutical company. Respondent, which is located in Torrance, California, sells a variety of products including over-the-counter medicines and dietary supplements. Among these products were ''Stona'' brand pseudoephedrine pills and liquid cold remedies that were made in Japan and Taiwan.

In March 2004, DEA was advised by a regulatory consultant to Respondent's U.S. subsidiary that the company had been importing and distributing several Stona brand pseudoephedrine products without the registrations required under the Controlled Substances Act. *See* 21 U.S.C. 823(h); *id.* 957(a) & 958(c)(2). At a meeting, the consultant further told several DEA Diversion Investigators (DIs) that Respondent had been importing and distributing products containing pseudoephedrine and phenylpropanolamine (PPA) for at least 10 years but that Respondent had stopped importing PPA products. According to the consultant, Respondent was never registered to either import or distribute List I chemicals because neither he (the consultant) nor the company knew that registration was required.

The investigation also determined that Respondent had sold pseudoephedrine products to other distributors who were not registered. Moreover, the investigative file states that Respondent failed to file form DEA–486, Import/Export Declaration, for its importations of the pseudoephedrine. *See* 21 CFR 1313.12(a).

Respondent also advised DEA that it had a sizeable inventory of pseudoephedrine products at its Torrance, California facility.[1] Respondent informed DEA that it had ''quarantined'' the inventory; it also requested authorization to export the products back to its facilities in Japan and Taiwan.

On August 9, 2004, DEA approved a one time distribution by Respondent to Leiner Health Products, a DEA registered exporter, for the purpose of returning the products. On or about August 27, 2004, the shipment occurred.

Thereafter, on September 29, 2004, Respondent applied for a DEA registration to distribute pseudoephedrine. On February 23, 2005, DEA conducted a pre-registration investigation at Respondent's Torrance facility. Respondent's officials told the DIs that it was seeking registration to distribute the remaining portion of the product that it had previously returned to Taiwan and which it had not been able to sell. In particular, Respondent sought authorization to import a one-time shipment of 7,000 bottles containing 24 tablets of 30 mg. pseudoephedrine from its Taiwan facility. Respondent's officials further told the DIs that it was no longer manufacturing pseudoephedrine products.

The DIs determined that Respondent had in place adequate procedures for identifying and verifying customers, recordkeeping and reporting, and for the handling and delivery of the products. The DIs also determined that Respondent would provide adequate security for the products.

The DIs also conducted verifications of Respondent's customers. Respondent's customers are a combination of small groceries, pharmacies, and medical providers that primarily serve Asian-American communities. Eighty percent of Respondent's customers are located in Southern California. The DIs also ran criminal background checks on Respondent's officers and found no derogatory information. The DIs further determined that with the exception of the conduct described above, Respondent was in compliance with applicable laws and had obtained a California permit for chemical precursors.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless the registration would be ''inconsistent with the public interest.'' In making this determination, Congress directed that I consider the following factors:

(1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) Compliance by the applicant with applicable Federal, State, and local law;

[1] The inventory included approximately 6992 bottles (120 ml.) of Stona cough syrup, 3915 packages of 24 Stona tablets, 2943 packages of 24 Stona caplets, and 720 packages of 24 Stona S caplets.

(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).[2]

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-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).

[2] 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.

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.

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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