

Discussion

Section 303(h) of the Controlled Substances Act (CSA) provides that “[t]he Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest.” 21 U.S.C. 823(h). 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;

(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 a registration should be denied. *See, e.g., David M. Starr*, 71 FR 39367, 39368 (2006); *Energy Outlet*, 64 FR 14269 (1999). Moreover, I am “not required to make findings as to all of the factors.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Having considered all of the factors, I conclude that factors two and four establish that Respondent’s registration would be “inconsistent with the public interest.” 21 U.S.C. 823(h). Respondent’s application will therefore be denied.

Here, the record establishes that between September 2005 and February 2006, Respondent illegally imported into the United States, 1,000 kilograms of Ma Huang extract, which contained ephedrine alkaloids in a concentration of approximately eight percent. While at the time of the importation, “harvested plant material * * * contain[ing] ephedrine * * * that preserve[d] the natural constituents in the ratios that are found in the plant’s natural state” was exempt from the CSA’s requirements, DEA’s regulation further provided that “[p]lant material subjected to chemical or physical extraction, concentration, chemical reaction, or other treatment that alters the plant’s natural constituents [was] not exempt.” 21 CFR

1310.12(d)(1).⁴ Respondent did not have a registration to import the product, which contains a list I chemical and was produced through an extraction process, and thus was not exempt from the application of the Act. *See* 21 U.S.C. 957(a); 21 CFR 1310.12(d)(1). Respondent’s importation of Ma Huang extract therefore violated federal law.

Moreover, substantial evidence establishes that Respondent, its owner (Mr. Wheat), and vice-president (Mr. Smith), violated the CSA by importing schedule III and IV controlled substances (including anabolic steroids, multiple benzodiazepines, as well as phentermine and zolpidem) into the United States from Belize in violation of 21 U.S.C. 952 and 957(a)(b). While the indictment sets forth only allegations, the plea agreements of several co-conspirators implicated Respondent, Mr. Wheat, and Mr. Smith, in the conspiracy to knowingly import controlled substances into the United States in violation of federal law. The agreements thus provide substantial evidence to support a finding that Respondent, Mr. Wheat, and Mr. Smith violated federal law.⁵ *See Richardson v. Perales*, 402 U.S. 389 (1971) (upholding use of hearsay evidence in administrative proceedings).

Accordingly, I conclude that granting Respondent’s application would be “inconsistent with the public interest.” 21 U.S.C. § 823(h).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h), as well as 28 CFR 0.100(b) & 0.104, I order that the application of Hi-Tech Pharmaceuticals, Inc., for a DEA Certificate of Registration to import ephedrine, a list I chemical, be, and it hereby is, denied. I further order that the application of Hi-Pharmaceuticals, Inc., for a DEA Certificate of Registration to

⁴ On July 25, 2007, DEA published an interim rule which removed the exemption “for unaltered ephedra plant material.” 72 FR 40738, 40741 (2007). This rule became effective on August 24, 2007. *Id.* at 40742.

⁵ In light of the evidence establishing that Mr. Wheat and Mr. Smith have committed offenses in violation of the CSA, I need not decide whether their prior convictions are too dated to be considered.

I further note that Respondent imported listed chemicals which it then used to manufacture and distribute products which a federal court has held were adulterated within the meaning of the Food, Drug, and Cosmetic Act. *See Hi-Tech Pharmaceuticals, Inc., v. Crawford*, 505 F.Supp.2d at 1357. *See also* 21 U.S.C. 823(h)(5) (directing consideration of “such other factors as are relevant to and consistent with the public health and safety”). This conduct also supports the conclusion that granting Respondent a registration would be “inconsistent with the public interest.” 21 U.S.C. 823(h).

manufacture ephedrine, a list I chemical, be, and it hereby is, denied. This order is effective April 28, 2008.

Dated: March 17, 2008.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E8–6377 Filed 3–27–08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on November 29, 2007, Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Phenylacetone (8501)	II
Coca Leaves (9040)	II
Opium, raw (9600)	II
Poppy Straw (9650)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances for the manufacture of controlled substances in bulk for distribution to its customers.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import crude opium, poppy straw, concentrate of poppy straw or coca leaves. As explained in the Correction to Notice of Application pertaining to Rhodes Technologies, 72 FR 3417 (2007), comments and requests for hearings on applications to import narcotic raw material are not appropriate.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), 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 being sent via regular mail should be addressed, in quintuplicate, to the Drug

Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, VA 22152; and must be filed no later than April 28, 2008.

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), 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: March 19, 2008.

Joseph T. Rannazzisi,

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

[FR Doc. E8-6375 Filed 3-27-08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

This is notice that on March 6, 2008, Penick Corporation, 33 Industrial Park Road, Pennsville, New Jersey 08070, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the basic classes of controlled substances listed in schedule II.

Drug	Schedule
Coca Leaves (9040)	II
Raw Opium (9600)	II
Poppy Straw (9650)	II
Concentrate of Poppy Straw (9670).	II

The company plans to import the listed controlled substances to manufacture bulk controlled substance intermediates for sale to its customers.

As noted in a previous notice published in the Federal Register on September 23, 1975, (40 FR 43745), 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: March 19, 2008.

Joseph T. Rannazzisi,

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

[FR Doc. E8-6376 Filed 3-27-08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated December 17, 2007 and published in the Federal Register on December 27, 2007, (72 FR 73357), Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in schedule II:

The company plans to import Phenylacetone for use as a precursor in the manufacturer of amphetamine only.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Cambrex Charles City, Inc. to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Cambrex Charles City, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with State and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: March 19, 2008.

Joseph T. Rannazzisi,

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

[FR Doc. E8-6368 Filed 3-27-08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated December 18, 2007 and published in the Federal Register on December 27, 2007, (72 FR 73359), Johnson Matthey, Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey 08066-1742, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Phenylacetone (8501)	II
Raw Opium (9600)	II
Concentrate of Poppy Straw (9670).	II

The company plans to import the listed controlled substances as raw materials for use in the manufacture of bulk controlled substances for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Johnson Matthey, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Johnson Matthey, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with State and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.