and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1309.31(a).

In 1996, Congress enacted the Comprehensive Methamphetamine Control Act of 1996, which, for the first time, subjected distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine products to the registration requirements. *See* 62 FR 52254 (1997) (final rule). To prevent disruption of the legitimate commerce in these products, DEA enacted a temporary exemption from registration for distributors of these products. *See* 62 FR at 5915 (interim rule).

Accordingly, with respect to distributors of combination ephedrine products, the exemption applies to ''each person required'' to be registered, ''provided that the person submit[ted] a proper application for registration on or before July 12, 1997.'' 21 CFR 1309.25(a). The regulation further provides that ''[t]he exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application.'' *Id.* DEA applied the same rule to distributors of pseudoephedrine and phenylpropanolamine, the only difference being that the application had to be submitted ''on or before October 3, 1997.'' *Id.* 1309.25(b).[6]

As found above, on July 29, 1997, Mr. Neil S. Abodabba applied for a registration to distribute ephedrine, pseudoephedrine, and phenylpropanolamine. GX 1. While Mr. Abodabba listed Memphis Wholesale Company as the applicant, the firm did not file its charter of incorporation with the Tennessee Secretary of State until April 14, 1998. GX 36, at 4; GX 30. As Memphis Wholesale did not exist as an independent legal entity until more than eight months later, the application submitted on July 29, 1997, is personal to Mr. Abodabba. Moreover, there is no evidence that Memphis Wholesale Company, Incorporated, has ever submitted an application for a DEA registration either under its original owner (Mr. Abodabba), or under its new owner (Mr. Issa). Likewise, there is no evidence that the application was amended to reflect that Memphis Wholesale Company, Inc., was the applicant.

While the evidence indicates that Mr. Issa disclosed to agency investigators during the 2002 inspection that he was Respondent's owner, the firm did not have authority to distribute under the temporary exemption because it was not the ''person'' who applied for registration in July 1997. *See, e.g.*, 21 CFR 1309.25(a). As the regulation makes plain: *[e]ach person* required by [21 U.S.C. 822] to obtain a registration to distribute * * * a combination ephedrine product is temporarily exempted from the registration requirement, provided that *the person* submits a proper application for registration on or before July 12, 1997.'' *Id.* (emphasis added).[7] Moreover, the authority Mr. Abodabba obtained to distribute (which was limited to pseudoephedrine and phenylpropanolamine) was not lawfully transferred to either the corporation or to its new owners) because the written consent of the Agency was never obtained. *See id.* 1309.63 (''No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.'').

Accordingly, I hold that Respondent has been without authority to distribute list I chemicals since July 16, 2001 (when Mr. Issa became its owner), and that all distributions it has made since that date (including all those listed in the compilation of its 2004 sales) have been in violation of federal law.[8] *See* 21 U.S.C. 822(a). I further hold that Respondent does not have an application pending before the agency.

Order

Pursuant to the authority vested in me under 5 U.S.C. 554(e) and 28 CFR 0.100(b) & 0.104, I hereby declare that since July 16, 2001, Memphis Wholesale Company, Incorporated, has not had authority under 21 CFR 1309.25 to distribute pseudoephedrine, combination ephedrine, and phenylpropanolamine. This Order is effective immediately.

Dated: March 17, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–6378 Filed 3–27–08; 8:45 am]

BILLING CODE 4410–09–P

[6] DEA regulations defined ''[t]he term person [as] includ[ing] any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.'' 21 CFR 1300.01(b)(34).

[7] While Respondent relies on Mr. Abodabba's application, it ignores that under 21 CFR 1309.25(a), this application was not timely submitted with respect to combination ephedrine products and thus, not even Mr. Abodabba was not entitled to the exemption. *See* GX 1 (application dated July 29, 1997).

[8] Mr. Abodabba is not a party to this proceeding, and I conclude that it is not necessary to decide whether Respondent's activities under his ownership were lawful. Moreover, to the extent this proceeding was brought to deny Mr. Abodabba's application, which is the only application in the record, *see* GX 1, service has not been properly effectuated. *See Jones* v. *Flowers,* 547 U.S. 220, 230 (2006) (''[T]he government's knowledge that notice pursuant to the normal procedure was ineffective triggered an obligation on the government's part to take additional steps to effect notice.''); *see also id.* at 232 (discussing *Robinson* v. *Hanrahan,* 409 U.S. 38, 39–40 (1972) (per curiam) (even though state law required vehicle owner to register his address with the state, ''we found that the State had not provided constitutionally sufficient notice, despite having followed its reasonably calculated scheme, because it knew that [the owner] could not be reached at his address of record'').

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hi-Tech Pharmaceutcals, Inc.; Denial of Applications

On August 16, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Hi-Tech Pharmaceuticals, Inc. (Respondent), of Norcross, Georgia. The Show Cause Order proposed the denial of Respondent's pending applications for DEA Certificates of Registration to import and manufacture ephedrine, a list I chemical, on the ground that its ''registrations would be inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4) & 958(c)).

The Show Cause Order specifically alleged that both Respondent's owner, Mr. Jared Wheat, and its Vice-President, Mr. Stephen D. Smith, had previously been convicted of controlled-substance felony offenses. *Id.* The Show Cause Order next alleged that on February 23, 2006, agents of the U.S. Customs Service and the Food Drug Administration (FDA) executed a search warrant at Respondent and seized various products containing ephedrine alkaloids that the company was manufacturing and distributing, as well as the raw materials used to manufacture these products. *Id.* at 2.

The Show Cause Order further alleged that Respondent operated several websites which represented that they offered controlled substances for sale from Canada and that the ''drugs were made using good manufacturing practices in Canada,'' when, in fact, ''Hi-Tech manufactured many of these drugs, including various Schedule III and IV controlled substances, in the country of Belize and unlawfully imported them into the United States without a DEA registration'' in violation of 21 U.S.C. 957(a) and 21 CFR 1301.11. *Id.* at 2. Relatedly, the Show Cause Order alleged that on September 7, 2006, a federal grand jury indicted

Respondent, Mr. Wheat, Mr. Smith, and ten other individuals associated with the company, charging them with, *inter alia*, ''the unlawful distribution of controlled substances and conspiracy to import controlled substances into the United States.'' *Id.*

On August 20, 2007, the Show Cause Order was served on Respondent by certified mail, return receipt requested. Thereafter, Respondent's counsel submitted a letter in which it waived its right to a hearing, but in which it also responded to several of the Show Cause Order's allegations. Ltr. of Joseph P. Schilleci, Jr., to Hearing Clerk, 1 (Sept. 14, 2007). The factual assertions and arguments presented in this letter will be considered pursuant to 21 CFR 1301.43(c).

I therefore conclude that Respondent has waived its right to a hearing. I therefore enter this Final Order without a hearing based on relevant material contained in the investigative file as well as Respondent's letter and make the following findings. *See* 21 CFR 1301.43(e).

Findings

On July 25, 2005, Respondent, a Georgia corporation, applied for two DEA registrations: one to import ephedrine and one to manufacture it. Ephedrine is a list I chemical, which is frequently diverted into the illicit manufacture of methamphetamine, a schedule II controlled substance. *See* 21 U.S.C. 802(34); *see also* 21 CFR 1308.12(d). Respondent's applications were submitted by Mr. Jared R. Wheat. On both applications, Respondent stated that ''Jared R. Wheat, [its] President and sole shareholder * * * was convicted on October 2, 1991[,] in the United States District Court, Northern District of Alabama * * * for conspiracy to distribute MDMA. He was sentenced to the custody of the Bureau of Prisons for thirty-six months (36) months [and] three years supervised release.'' [1]

During the course of DEA's pre-registration investigation, agency investigators received information that several other federal agencies including the FDA and Federal Trade Commission were also investigating Respondent. Moreover, during an on-site inspection, Mr. Wheat told DEA investigators that he was currently importing ephedra or Ma Huang Extract. He also provided DEA investigators with a ''Certificate of Analysis'' which indicated that Respondent had imported from Sinochem Jiangsu Import & Export Corporation of Nanjaing, China, one thousand kilograms of Ma Huang Extract containing 8.2% total ephedrine alkaloids.[2] The Certificate stated that ''[t]his product is concentrated from natural sources and does not contain either synthetic or fermentation source. All alkaloids are results from extraction and concentration of crude plant material.'' The Certificate also noted that ''water'' was used as the ''extract solvent.''

On February 23, 2006, investigators from FDA and U.S. Customs executed a search warrant at Respondent's building. The FDA investigators seized various products. Simultaneously, the United States Attorney filed a complaint for forfeiture against various products which the FDA had seized on the ground that they were adulterated. These products were labeled as ''Lipodrene,'' ''Stimerex-ES,'' and ''Betradene,'' and each of the products indicated that they contained 25 mg. of ephedrine alkaloids in each tablet. Subsequently, the U.S. District Court for Northern District of Georgia rejected Respondent's contentions and granted the Government's motion for summary judgment on its complaint for forfeiture. *Hi-Tech Pharmaceuticals, Inc.* v. *Crawford*, 505 F.Supp.2d 1341 (N.D. Ga. 2007).[3]

On September 7, 2006, a federal grand jury returned a forty-five count indictment against Respondent, Jared Wheat, Stephen D. Smith, and nine other individuals. The indictment alleged, *inter alia*, that the defendants had conspired to manufacture in Belize and intentionally import, or attempt to import, into the United States, schedule III controlled substances (the steroids oxandrolone, oxymetholone, stanazolol) and schedule IV controlled substances (alprazolam, diazepam, lorazepam, phentermine, and zolpidem), in violation of 21 U.S.C. 952(a)(2), 960(a)(1), 960(b)(4), and 963. *United States* v. *Wheat, et al.*, No. 1:06CR382 (N.D. Ga.) (Indictment at 14–16, 23–24). The indictment also alleged that Respondent, Mr. Wheat, Mr. Smith, and others, knowingly and intentionally imported phentermine, Xanax (alprazolam), and Ambien (zolpidem) on various dates between February and May 2004. Indictment at 30–31.

Regarding the indictment, Respondent's counsel stated that it ''is confident that the facts will show that it has been and is appropriately conducting its business within the bounds of the law.'' Letter of Respondent's Counsel, at 1. Respondent's counsel further contended that the indictment's allegations ''are incorrect and do not portray an accurate description of [it], either in the past or present,'' and ''that there is no basis for the Government's indictment of Hi-Tech.'' *Id.*

The investigative file establishes, however, that several of the defendants named in the indictment have entered guilty pleas to various counts. As part of his plea agreement, B.W. admitted that he conspired with Wheat, Smith, and Respondent, ''to knowingly and intentionally import and attempt to import into the United States from Belize [the] Schedule IV controlled substances * * * [a]lprazolam, [d]iazepam, [l]orazapam, [p]hentermine, and [z]olpidem * * * all in violation of federal law.'' B.W. Guilty Plea and Plea Agreement at 1–2. B.W. further admitted that he ''had knowledge of attempts to import Schedule IV controlled substances and [that he] assisted in the manufacture of [these substances] on two (2) occasions.'' *Id.* at 2.

Defendant D.W. admitted that he conspired with Wheat and Smith ''to knowingly and intentionally import and attempt to import into the United States from Belize anabolic steroids, Schedule III controlled substances, and to knowingly and intentionally import and attempt to import into the United States from Belize [the] Schedule IV controlled substances * * * [a]lprazolam, [d]iazepam, [l]orazepam, [p]hentermine and [z]olpidem * * * all in violation of federal law.'' D.W. Guilty Plea and Plea Agreement at 1. Finally, Defendant D.J. admitted in his plea agreement that he had knowledge that Wheat, Smith, Respondent, and others, ''did knowingly and intentionally * * * conspire * * * with each other and others to knowingly and intentionally import and attempt to import into the United States from Belize [the] Schedule IV controlled substances * * * [a]lprazolam, [d]iazepam, [l]orazepam, [p]hentermine and [z]olpidem * * * in violation of'' federal law. D.J. Guilty Plea and Plea Agreement at 1–2.

[1] The investigative file also indicates that in September 1992, Mr. Smith was convicted in the Georgia Superior Court of purchasing or possession of a controlled substance. As the letter from Respondent's counsel indicated, Mr. Smith ''is a Vice-President of [Respondent but] does not own any shares in'' the company.

[2] During the inspection, Mr. Wheat provided the DIs with a product list and invoice which showed that it was manufacturing and distributing several products which contained ephedrine alkaloids. Each of the products had an ephedrine alkaloid content of less than five percent.

[3] Regarding the seizure of ephedrine alkaloid products from Respondent, its counsel admitted that ''on August 15, 2007, the United States District Court for the Northern District of Georgia entered judgment in favor of the FDA.'' Ltr. of Joseph P. Schilleci, Jr., to Hearing Clerk, at 1 (Sept. 14, 2007). Respondent's counsel further stated that it was appealing the district court's decision. *Id.*

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 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]

BILLING CODE 4410–09–P

[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).

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