

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. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: March 19, 2008.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 17, 2007, and published in the **Federal Register** on December 27, 2007, (72 FR 73358), GE Healthcare, 3350 North Ridge Avenue, Arlington Heights, Illinois 60004-1412, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Cocaine (9041), a basic class of controlled substance listed in schedule II.

The company plans to manufacture a radioactive product used in diagnostic imaging in the diagnosis of Parkinson's Disease and for manufacture in bulk for investigational new drug (IND) submission and clinical trials.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of GE Healthcare to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated GE Healthcare 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. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer 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.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 20, 2007, and published in the **Federal Register** on December 31, 2007, (72 FR 74331), Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Oripavine (9330), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance in bulk for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Chattem Chemicals, Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Chattem Chemicals, 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. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer 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. E8-6412 Filed 3-27-08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05-38]

Memphis Wholesale Company; Declaratory Order Terminating Exemption From Registration

On July 12, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Memphis Wholesale Company (Respondent) of Memphis, Tennessee. Show Cause Order at 1. The Show Cause Order proposed the denial of what it referred to as Respondent's "application" for a registration as a distributor of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine (PPA), and to revoke any exemption from registration, on the ground that its registration "is inconsistent with the public interest." *Id.*

The Show Cause Order specifically alleged that "[o]n July 29, 1997, Memphis Wholesale Company, by its owner, Neal Abodabba," applied for a DEA Certificate of Registration, that a control number was assigned to its application "permitting the firm to temporarily operate under the regulatory exemption [provided] at 21 CFR 1309.25, pending agency action on the application." *Id.* at 2. The Show Cause Order alleged that in "April 1999, Memphis Wholesale Company was incorporated in the State of Tennessee by Neal Abodabba and Shawkat Abodabba, without notification to DEA that the form of ownership, and thus the registered person, had changed." *Id.*

The Show Cause Order next alleged that on August 10, 2000, DEA investigators conducted an inspection of Respondent. *Id.* The Order alleged that during the inspection, Mr. Neal Abodabba told investigators "that 7.8% of his total sales were for 'energy' products, which included Max Brand and Mini-Thins," which are listed chemical products. *Id.* The Order also alleged that Mr. Abodabba also told investigators that his customers included approximately 200 to 300 convenience stores and gas stations, which were located in Tennessee, Arkansas, and northern Mississippi, and that most of these customers purchased listed chemical products from him. *Id.*

The Show Cause Order further alleged that "in July 2000, Memphis Wholesale had begun consolidating its deliveries in the Nashville area by shipping to [an] unlicensed distributor, Nashville Wholesale, for further distribution to retailers * * * in violation of 21 U.S.C.

841(f) and 843(a)(9).” *Id.* Finally, with respect to the August 2000 inspection, the Show Cause Order alleged that DEA investigators conducted an accountability audit for the period February 1, 2000, through August 10, 2000, and found overages in various products. *Id.* at 2–3.

The Show Cause Order next alleged that on May 16, 2002, DEA investigators conducted another inspection of Respondent. *Id.* at 3. According to the Show Cause Order, during the inspection, “Mr. Mohammed Issa represented himself as the owner of Memphis Wholesale,” and subsequently the investigators were informed by Mr. Abodabba “that he had ‘sold his shares’ in [the firm] to Mohammed Issa.” *Id.* Relatedly, the Show Cause Order alleged that Respondent “is now improperly operating as a chemical distributor under the control of Mr. Issa,” and that “[n]either Mr. Abodabba nor Mr. Issa notified DEA of any corporate ownership changes.”¹ *Id.*

Following service of the Show Cause Order, Respondent requested a hearing on the allegations and the matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. Counsel for both parties agreed, however, that in lieu of a hearing at which witnesses would be called, they would submit affidavits, proffers of testimony, and other evidence. ALJ at 4. Neither party objected to any of the evidence or proffers submitted. After both parties submitted briefs, the ALJ issued her recommended decision.

In her decision, the ALJ found that Respondent was not entitled to operate under the temporary exemption from registration authorized under 21 CFR 1309.25, because neither Respondent, which was incorporated in 1998, nor Mr. Issa (the corporation’s current owner), “was the same ‘person’ that applied for registration in 1997.” ALJ at 21. The ALJ thus reasoned that Respondent was “not entitled to operate under the exemption granted to the business that Mr. Abodabba owned in 1997.” *Id.* The ALJ further found that “since 1998, Respondent has been distributing listed chemical products without being registered to do so, in violation of 21 U.S.C. 822(a)(1).” *Id.*

“In light of these findings,” the ALJ concluded that “a further finding would be warranted that there is no viable application pending.” *Id.* She nonetheless concluded that it was

appropriate to make findings under the public interest factors (*see* 21 U.S.C. 823(h)) because “the parties have devoted substantial resources to this case.” ALJ at 21. Upon analyzing the factors, the ALJ concluded that Respondent’s registration would be inconsistent with the public interest. ALJ at 24.

Having considered the record as a whole, I hereby issue this declaratory order. *See* 5 U.S.C. 554(e). I conclude that the original exemption from registration obtained by Mr. Abodabba terminated no later than the date he transferred his ownership interest in Respondent to Mr. Issa. I further conclude that while the application which Mr. Abodabba submitted on July 29, 1997, listed “Memphis Wholesale Company” as the applicant, because the entity was not then incorporated it did not have independent legal capacity to seek a registration and the application is therefore personal to Mr. Abodabba. While the evidence establishes that Mr. Abodabba has long since sold his interest in Respondent and is not in business at the proposed registered location, to the extent this proceeding seeks to adjudicate his application, the Government has known since 2002 that Mr. Abodabba was no longer at that location and has not properly served him.² To the extent Respondent (under its new owner) seeks to adjudicate its entitlement to a registration, Respondent has never submitted an application. Accordingly, there is no pending application to act upon. I make the following findings.

Findings

On July 29, 1997, Neal S. Abodabba, submitted an application for a registration to distribute the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine. GX 1. On the application, Mr. Abodabba indicated that Memphis Wholesale Company was the applicant. *Id.* However, the business was not then incorporated and did not file its charter with the Tennessee Secretary of State until April 14, 1998. GX 36, at 2.

On May 16, 2002, DEA investigators went to Respondent to conduct an inspection. On that date, Mr. Mohammed Issa told investigators that he owned Respondent. Gov’t Proffer of Testimony at 6. Moreover, in its proffer, Respondent stated that “Mr. Issa would testify that he is the majority stockholder of Memphis Wholesale

Company and that he became majority stockholder on July 16, 2001.” Respondent’s Summary of Position at 2. Furthermore, on July 17, 2002, Respondent filed its annual report with the Tennessee Secretary of State which stated that Mohammed Issa was the corporation’s president, Sameer Issa was its secretary, and Bill Miller was its treasurer.³ GX 36, at 10. The report further indicated that its board of directors was comprised of the same three individuals.⁴ *Id.*

Respondent submitted into evidence a compilation and serial listing of its sales of listed chemical products for the period January through December 2004. According to a table which is attached to this document, during 2004, Respondent had sales of all products totaling \$4,134,004.28; its list I chemical products constituted 7.09 percent of its sales. The document (which is 143 pages in length) then lists by product, numerous instances in which Respondent sold ephedrine and pseudoephedrine products to gas stations and convenience stores. *See generally* Memphis Wholesale Company, Inc., Sales by Item Detail, at 1–143. According to the list, during 2004, Respondent’s sales of these products totaled \$225,167.30. *See id.* at 143.

Discussion

Under 21 U.S.C. 822(a)(1), “[e]very person who * * * distributes any * * * list I chemical, or who proposes to engage in the * * * distribution of any * * * list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.”⁵ Furthermore, “[p]ersons registered by the Attorney General * * * to distribute * * * list I chemicals are authorized to possess [and] distribute * * * such * * * chemicals * * * to the extent authorized by their registration and in conformity with the other provisions of” Subchapter I of the Controlled Substances Act. *Id.* 822(b). DEA regulations further provide that “[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is approved

³ On April 16, 2001, Respondent filed its annual report which indicated that Neal Abodabba was its president and Shawkat Abodabba was its Secretary.

⁴ On its annual report which it submitted on May 10, 2004, Respondent no longer listed Mr. Miller as either a corporate officer or director. Instead, the report listed “K. Issa” as an officer and director. GX 36, at 12.

⁵ Ephedrine, pseudoephedrine and phenylpropanolamine are list I chemicals. *See* 21 U.S.C. 802(34).

¹ The Show Cause Order also raised various allegations related to the diversion of ephedrine and pseudoephedrine from non-traditional retailers into the illegal manufacture of methamphetamine, a schedule II controlled substance. Show Cause Order at 1–2; *see also* 21 CFR 1308.12(d).*Id.*

² *See Nashville Wholesale Company, Inc.*, 71 FR 52159, 52160 (2006) (noting that Mr. Abodabba was served at the proposed registered location of Nashville Wholesale Company).

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

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”).

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]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hi-Tech Pharmaceuticals, 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

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).