dispensed more than 25,000 dosage units of controlled substances without a physician's authorization. The then-Acting Deputy Administrator did not find Respondent's explanation persuasive regarding the unauthorized dispensing of controlled substances. The then-Acting Deputy Administrator's findings regarding the previous revocation are *res judicata* for purposes of this proceeding. *See Stanley Alan Azen, M.D.,* 61 FR 57893 (1996), *Liberty Discount Drugs, Inc.,* 57 FR 2788 (1992).

Louie Grimes is now the owner of Respondent. However, Louis Grimes was also a pharmacist at Respondent, working three days a week, during 1990 to 1992, when the above violations occurred. Louie Grimes insists that he never dispensed a controlled substance in violation of Federal laws and regulations. But, the Government presented evidence that Louie Grimes was responsible for the unlawful dispensation of approximately 1,400 dosage units of controlled substances.

Louie Grimes' contention that the physicians were mistaken and that they had in fact authorized the prescriptions in question was rejected by the then-Acting Deputy Administrator, and his conclusions are binding for purposes of this proceeding.

Louie Grimes' other contention that his initials appeared next to unauthorized dispensations because changes were not made in the computer is also rejected by the Deputy Administrator. The Daily Transaction Report generated by Respondent for May 22, 1991, shows that, at least on that day, the pharmacist's initials were changed throughout the day. Further, Louie Grimes' own testimony at the hearing was contradictory. On the one hand, he maintained that Respondent's computer program made it impossible to be certain who dispensed a controlled substance prescription when two pharmacists were on duty at the same time. But, he also testified that he was ''a hundred percent'' certain that he was always in compliance with State and Federal laws requiring that the dispensing pharmacist's initials appear next to each dispensation in the pharmacy's records.

As Judge Bittner noted, this explanation was first raised at that hearing. Judge Bittner concluded that ''Louie Grimes' testimony regarding Respondent's computer program was a last-ditch attempt at avoiding responsibility for his actions during the relevant time period and that Louie Grimes did in fact on numerous occasions dispense controlled substances without a physician's authorization, or refill a prescription more than five times or after six months from its original issuance.''

Regarding factor three, there is no evidence that Respondent or its owner or employees have ever been convicted under State of Federal laws relating to the manufacture, distribution, or dispensing of controlled substances.

As to factor five, the Government contends that the legitimacy of the transfer of Respondent from Joseph Grimes to Louie Grimes and also the role that Joseph Grimes will play in Respondent's future management should be considered. ''The [Deputy] Administrator has long held that applications for registration should be denied where there is a likelihood that a transfer of ownership or control of business is actually an attempt to contravene the effects of a revocation.'' *Hilltop Pharmacy,* 53 FR 35936 (1988) (citing *Darrow Drug, Inc.,* 49 FR 39246 (1984)). Similarly, the Deputy Administrator may look to who exerts influence over the registrant; sometimes the bonds linking the former owner to the new owner are too close to ensure that the former owner will have no influence over the operation of the pharmacy. *See Monk's Pharmacy,* 52 FR 8988 (1987), *Carriage Apothecary,* 52 FR 27599 (1987).

Judge Bittner did not make findings regarding the legitimacy of the transfer of ownership since the Government did not pursue this issue but instead focused on the immediate and potential future effect of the transfer. The then-Acting Deputy Administrator found that during the time that Joseph Grimes was Respondent's owner and managing pharmacist, Respondent ''failed miserably in its responsibility as a DEA registrant.'' Joseph Grimes continues to receive employment, salary and rent from Respondent. In addition, he holds a reversionary interest in Respondent. Therefore the Deputy Administrator concludes that Joseph Grimes continues to derive a benefit from Respondent's operation. The Deputy Administrator agrees with judge Bittner that ''Joseph Grimes' continued interest in Respondent, considered in conjunction with the Grimes' familial relationship and the nominal consideration for the life estate, lead * * * to the conclusion that the bonds linking Joseph Grimes with Louie Grimes and Respondent are too close to ensure that Joseph Grimes will have no influence in the operation of Respondent.''

The Deputy Administrator agrees with Judge Bittner's conclusion that Respondent's registration would be inconsistent with the public interest. From 1990 to 1992, Respondent could not account for over 80,000 dosage units of controlled substances and dispensed more than 25,000 dosage units of controlled substances without a physician's authorization. During that time, Louie Grimes worked three days a week as a pharmacist at Respondent and some of the unauthorized dispensations are attributable to Louie Grimes. Yet Louie Grimes continues to lay blame elsewhere, with the physicians or the computer program, rather than accept responsibility for his actions. In addition, Respondent did not present any persuasive evidence of meaningful procedural changes since 1992 that would ensure that it will not again fail to account for controlled substances or dispense controlled substances without authorization. Further, the Deputy Administrator is troubled by Joseph Grimes' continued involvement with Respondent and his reversionary interest in Respondent.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for registration, executed by Respondent, be, and it hereby is , denied. This order is effective November 2, 1999.

Dated: October 25, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99–28602 Filed 11–1–99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 5, 1999, and published in the **Federal Register** on August 20, 1999 (64 FR 45565), ISP Freetown Acquisition Corp., 238 South Main Street, Freetown, Massachusetts 02702 which has changed its name to ISP Freetown Fine Chemicals Inc. made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of 2,5-Dimethoxyamphetamine (7396), a basis class of controlled substance listed in Schedule I.

This firm plans to manufacture bulk 2,5-Dimethoxyamphetamine of conversion into a noncontrolled substance.

A registered bulk manufacturer of 2,5-Dimethoxyamphetamine filed written comments requesting that DEA not grant a registration because of the already existing adequate competition and supply in the domestic market, and

significant diversion risks. Review of the APA's definitions of license and licensing reveals that the granting or denial of a manufacturer's registration is a licensing action, not a rulemaking. Courts have frequently distinguished between agency licensing actions and rulemaking proceedings. *See, e.g. Gateway Transp. Co.* v. *United States*, 173 F. Supp. 822, 828 (D.C. Wis. 1959); *Underwater Exotics, Ltd.* v. *Secretary of the Interior*, 1994 U.S. Dist. LEXIS 2262 (1994) Courts have interpreted agency action relating to licensing as not falling within the APA's rulemaking provisions.

DEA has considered the factors in Title 21, United States Code, Section 823 (a) and the objector's arguments, and determined that the registration of the ISP Freetown Fine Chemicals Inc. to manufacture 2,5-Dimethoxyamphetamine is consistent with the public interest at this time. DEA has investigated the firm to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the applicant's physical security systems, verification of the applicants compliance with state and local laws, and review of the firm's background and history.

Under Title 21, Code of Federal Regulations, Section 1301.33b, DEA is not required to limit the number of manufacturers solely because a smaller number is capable of producing an adequate supply provided effective controls against diversion are maintained. DEA has determined that effective controls against diversion will be maintained by ISP Freetown Fine Chemicals Inc.

Therefore, pursuant to 21 U.S.C. Section 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of 2,5-Dimethoxyamphetamine is granted.

Dated: October 27, 1999.

John H. King,

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

[FR Doc. 99–28604 Filed 11–1–99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 98–37]

NVE Pharmaceuticals, Inc.; Denial of Applications

On July 14, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to NVE Pharmaceuticals, Inc. (Respondent), notifying it of an opportunity to show cause as to why DEA should not deny its May 7, 1997 applications for registration as an exporter of List I chemicals pursuant to 21 U.S.C. 958(c) and as a manufacturer for distribution of List I chemicals pursuant to 21 U.S.C. 823(h), for reason that such registration would be inconsistent with the public interest.

Respondent timely filed a request for a hearing on the issues raised by the Order to Show Cause. The hearing was held in Newark, New Jersey on December 3, 1998, before Administrative Law Judge Gail A. Randall. At the hearing, the Government called witnesses to testify and introduced documentary evidence. Respondent introduced documentary evidence, however it did not call any witnesses to testify. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument. On June 17, 1999, Judge Randall issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision, recommending that Respondent's applications for registration be denied. Neither party filed exceptions to Judge Randall's Recommended Rulings, Findings of Fact, Conclusions of Law and Decision, and on July 21, 1999, Judge Randall transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, except as specifically noted, the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge. His adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that Respondent was incorporated in 1986 with Robert Occhifinto as its president. Respondent is a manufacturer and distributor of over-the-counter pharmaceutical products and nutritional vitamins, including diet and exercise supplements. Some of the products that Respondent manufactures and sells contain, in whole or in part, the listed chemicals ephedrine, pseudoephedrine, and phenylpropanolamine (PPA). Respondent employs over 70 individuals, many of whom are extremely handicapped. As early as 1997, Respondent established a position for a ''Regulatory Affairs'' representative who is responsible for ensuring that Respondent complies with regulatory requirements.

Mr. Occhifinto is involved in numerous community and religious activities. He donates his time and personal resources to a variety of causes, and is also responsible for transforming a toxic waste site into a productive business complex.

The Deputy Administrator finds that ephedrine, pseudoephedrine and PPA are all List I chemicals that have legitimate uses, but they can also be used in the illicit manufacture of controlled substances. Ephedrine and pseudoephedrine can be used to manufacture methamphetamine, a Schedule II controlled substance that is a very potent central nervous system stimulant. Abuse of methamphetamine is a growing problem in the United States. The chemicals needed to manufacture methamphetamine are readily accessible at almost any pharmacy or retail store that sells pharmaceutical products. Ephedrine and pseudoephedrine extracted from over-the-counter products is often used in the illicit manufacture of methamphetamine.

In an effort to curb the use of licit chemicals in the illicit manufacture of controlled substances, Congress amended the Controlled Substances Act in 1988 with the passage of the Chemical Diversion and Trafficking Act (CDTA). Pub. L. 100–690, 102 Stat. 4181 (1988). The CDTA required that records and reports be made of certain transactions involving various chemicals. However, products containing ephedrine and pseudoephedrine were exempt from the recordkeeping and reporting requirements because they were approved for marketing under the Federal Food, Drug, and Cosmetic Act. The CDTA also made it illegal to distribute a listed chemical ''knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance * * *.'' *See* 21 U.S.C. 841(d)(2).

In November 1990, the DEA office in San Francisco discovered four 25