Boulevard, Chicago, Illinois 60604–3590 (contact Jeffery Trevino (312–886–6729)). A copy of the proposed consent decree may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044. In requesting a copy, please refer to the referenced case and DOJ Reference Number and enclose a check in the amount of $10.25 for the consent decree only (41 pages at 25 cents per page reproduction costs), or $17.50 for the consent decree and its appendices (70 pages), made payable to the Consent Decree Library.

Joel Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 99–28558 Filed 11–1–99; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 98–20]

City Drug Co.; Denial of Application

On February 24, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to City Drug Company (Respondent) of Opp, Alabama, notifying it of an opportunity to show cause as to why DEA should not deny its application for registration as a retail pharmacy under 21 U.S.C. 823(f), for reason that such registration would be inconsistent with the public interest.

By letter received by DEA on March 30, 1998, Respondent requested a hearing on the issues raised by the Order to Show Cause. Following prehearing procedures, a hearing was held in Mobile, Alabama on October 28, 1998, before Administrative Law Judge Mary Ellen Bittner. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted proposed findings of fact, conclusions of law, and argument. On June 30, 1999, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's application for a DEA Certificate of Registration be denied. Neither party filed exceptions to Judge Bittner's opinion and on August 10, 1999, Judge Bittner 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, in full, the Opinion and Recommended Ruling, 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 is a pharmacy that is located in Opp, Alabama. Joseph Grimes was Respondent's owner and pharmacist in charge until November 12, 1997. Respondent previously possessed DEA Certificate of Registration AC5430450, which was revoked, following a hearing, by the then-Acting Deputy Administrator in a final order dated October 7, *1997,* and effective November 13, 1997. See 62 FR 53338 (October 14, 1997).

In revoking Respondent's previous DEA registration, the then-Acting Deputy Administrator concluded that a 1992 investigation revealed that between January 1990 and January 1992, Respondent violated 21 U.S.C. 829 and 21 CFR 1306.04 by dispensing over 25,000 dosage units of controlled substances without a physician's authorization. The then-Acting Deputy Administrator based this conclusion on affidavits submitted by 11 physicians who reviewed prescriptions found at Respondent that were attributed to them, compared these prescriptions to their patient charts, and then swore that they had not authorized the prescriptions. The then-Acting Deputy Administrator found unpersuasive Respondent's argument that the physicians had forgotten to note the issuance of the prescriptions in the patient charts, stating that it was ''highly unlikely that eleven different physicians forgot to note numerous prescriptions in the patient charts which accounted for the dispensing of over 25,000 dosage units of controlled substances.'' The then-Acting Deputy Administrator also found that the patients' affidavits submitted by Respondent were less reliable than the physicians' affidavits since the physicians' affidavits were ''based upon a review of [their] patient records which were prepared and maintained during the relevant time period, whereas the patients' affidavits [were] based upon their recollection more than six years after the event.''

The then-Acting Deputy Administrator further concluded that Respondent violated 21 U.S.C. 827, by failing to maintain complete and accurate records of controlled substances, as evidenced by Respondent's inability to account for more than 80,000 dosage units of Schedule III and IV substances, and to explain an overage of 859 dosage units of oxycodone 5 mg., the only Schedule II controlled substance that was audited.

In revoking Respondent's previous DEA Certificate of Registration, the then-Acting Deputy Administrator states that:

> (Joseph) Grimes has failed to acknowledge that he and his pharmacy have done anything improper. An unexplained shortage of 80,000 dosage units and the unauthorized dispensation of over 25,000 dosage units of controlled substances are not merely minor technical violations. The egregious nature of the violations in this matter demonstrate that Respondent has failed miserably in its responsibility as a DEA registrant to protect against the diversion of controlled substances from the legitimate chain of distribution.

Id. at 53343.

On November 12, 1997, the day before the effective date of the revocation of Respondent's previous DEA Certificate of Registration, Joseph Grimes executed a Bill of Sale that transferred, ''in consideration of *ten dollars and other good and valuable consideration,*'' a life estate in Respondent to Louie Grimes. Louie Grimes is Joseph Grimes' nephew and is also a pharmacist. The ''other good and valuable consideration'' noted in the Bill of Sale was an oral agreement that Joseph Grimes would continue to work at Respondent two days per week in return for $1,500 per month, and that he would also receive rent of $1,500 per month on the building in which the pharmacy is located. According to the attorney who drafted and notarized the Bill of Sale, Louie Grimes may transfer his life estate in Respondent but that the pharmacy would revert back to Joseph Grimes upon his nephew's death.

Louie Grimes testified that when he took over operation of Respondent he withdrew the funds from the pharmacy's bank account and used those funds to open a new account in a different bank in Respondent's name. The utilities and business license fees are paid from this account, and Joseph Grimes is not authorized to sign any business check for Respondent. However, Louie Grimes was unaware that the utilities for the property where Respondent is located are listed in Joseph Grimes' name.

On November 13, 1997, Louie Grimes executed the application that is the subject of these proceedings on behalf of Repondent. On the application, Louie Grimes answered ''No'' to a question which asked whether ''the applicant ever surrendered or had a Federal controlled substance registration revoked.''

At the hearing regarding Respondent's pending application for registration, evidence was presented from the 1992 investigation concerning Louie Grimes' involvement in the operation of Respondent at that time. During the execution of the search warrant at Respondent on March 2, 1992, Joseph Grimes indicated that Louie Grimes worked part-time at Respondent as a pharmacist. According to Louie Grimes, he worked three days a week and Joseph Grimes worked three days a week during the relevant time period. As discussed above prescription records were seized from Respondent and DEA investigations generated a computer report with information from these prescriptions, including the initials of the dispensing pharmacist. This information was later shown to eleven physicians who allegedly authorized a number of the prescriptions. Each of these physicians, after reviewing their patient charts, swore in written declarations that they did not prescribe most of the controlled substances attributed to them. The declarations of two of the physicians indicated that Louie Grimes dispensed 870 dosage units of controlled substances that they had not authorized. In addition, the declarations revealed eight instances, when Louie Grimes refilled controlled substance prescriptions more than five times or more than six months after issuance of the original prescription in violation of 21 U.S.C. 829(b), for a total of 550 dosage units.

Louie Grimes testified at the hearing that he never dispensed a controlled substance without a physician's authorization and that he never refilled a controlled substance prescription more than five times or after six months from its being issued. In an effort to refute the physicians' declarations, Louie Grimes argued that nurses frequently telephone in prescriptions for physicians to pharmacies and in these instinces probably failed to note them in the patient charts. This explanation was rejected by the then-Acting Deputy Administrator in revoking Respondent's previous DEA registration as unlikely given the volume of authorized dispensation.

Louie Grimes also argued that another possible explanation for his initials appearing next to the unauthorized prescriptions is that Respondent uses (and used during the relevant time period) a pharmacy software program to track prescriptions that requires the pharmacist on duty to enter his initials into the computer when he begins work. According to Louie Grimes, these initials remain in the system until the user exits the program or a pharmacist affirmatively changes the initials. Therefore if two pharmacists were on duty at the same time, one could not be absolutely sure which pharmacist filled a particular prescription.

However, the Government entered into evidence a ''Daily Transaction Report'' created by Respondent for May 22, 1991, which lists orginal prescriptions in the order that they were dispensed at the pharmacy and the initials of the pharmacist that allegedly filled each prescription. This report indicates that Louie Grimes dispensed ten original prescriptions, Joseph Grimes then dispensed three original prescriptions, Louie Grimes then dispensed another four original prescriptions, and finally Joseph Grimes dispensed another ten original prescriptions.

Louie Grimes testified at the hearing that although the Alabama State Board of Pharmacy required pharmacies to maintain a Daily Transaction Report on which the dispensing pharmacist for each prescription is identified by his initials, he could not be completely sure which pharmacist dispensed controlled substances at any given time. However, he also testified that ''we could pretty much go by initials,'' and that he believed that during the relevant time period, Respondent complied with 21 CFR 1304.24 and 1306.22, which required a pharmacy to maintain certain information, including the initials of the pharmacist who dispenses or refills a controlled prescription.

After receiving Respondent's November 12, 1997 application for registration, DEA investigated whether ownership of Respondent had in fact been transferred. Louie Grimes produced documents pertaining to the transfer of ownership and a copy of his State pharmacy permit. As of November 13, 1997, Respondent has not been authorized to dispense controlled substances. Louie Grimes works as the pharmacist at Respondent four days per week and Joseph Grimes is the pharmacist two days per week. However, should Respondent become registered with DEA, Respondent would need a waiver of 21 CFR 1306.04(a) to continue to employ Joseph Grimes with access to controlled substances, in light of the earlier revocation of Respondent's DEA Certificate of Registration.

Louie Grimes testified at the hearing in this matter that he has taken certain measures to ensure that no prescription drugs are dispensed without a prescription authorized by a physician. Specifically, he testified that for oral prescriptions, he notes the person who called in the prescription and the time of the call. Further, Respondent no longer uses doctors' prescription pads to reduce oral prescriptions to writing.

A DEA investigator testified at the hearing that she had not received any complaints regarding Louie Grimes from physicians or the general public. Louie Grimes testified that he has never been charged with a crime and has never had any action taken against him by DEA or the State of Alabama. He further testified that he has never received any complaints from customers or anyone else regarding his conduct as a pharmacist.

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA Certificate of Registration if he determines that the granting of a registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable state, federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

Regarding factor one, it is undisputed that Respondent is currently licensed to handle controlled substances in Alabama. But as Judge Bittner noted, ''inasmuch as State licensure is a necessary but not sufficient condition for a DEA registration, * * * this factor is not determinative.''

Factors two and four, Respondent's experience in the dispensing of controlled substances and its compliance with applicable laws, are clearly relevant in this matter in determining the public interest. Respondent's previous DEA registration was revoked based upon the then-Acting Deputy Administrator's findings that Respondent could not account for over 80,000 dosage units of controlled substances and that the Respondent had

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]

BILLING CODE 4410–09–M

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