above restriction. This order is effective December 10, 1996.

Dated: December 2, 1996.

James S. Milford,

*Acting Deputy Administrator.*

[FR Doc. 96–31252 Filed 12–9–96; 8:45 am]

**BILLING CODE 4410–09–M**

**[Docket No. 95–4]**

## Roger Pharmacy; Revocation of Registration

On October 7, 1994, the Deputy Assistant Administrator. Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to show Cause to Roger Pharmacy (Respondent) of Gahanna, Ohio, notifying the pharmacy of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, BR1448655, and deny any pending applications for renewal of such registration as a retail pharmacy under 21 U.S.C. 823(f), for reason that the pharmacy's continued registration would be inconsistent with the public interest pursuant to 21 U.S.C. 824(a)(4).

On November 2, 1994, the Respondent, through counsel, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in Cleveland, Ohio on June 27, 1995, before Administrative Law Judge Mary Ellen Bittner. At the hearing, both parties called witnesses to testify, and the Government introduced documentary evidence. After the hearing, counsel for both parties submitted proposed findings of fact, conclusions of law and argument. On April 9, 1996, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's DEA Certificate of Registration be revoked. Neither party filed exceptions to her decision, and on May 10, 1996, Judge Bittner transmitted the record of these proceedings to the Deputy Administrator.

The Acting 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 Acting Deputy Administrator adopts, in full, the Findings of Fact, Conclusions of Law, and Recommended Ruling of the Administrative Law Judge, and 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 Acting Deputy Administrator finds that Jon R. Martin, R.Ph. purchased Respondent pharmacy, located in Gahanna Ohio, in the late 1980's. Respondent is a high volume drug store that employees 10 to 15 individuals, and provides services not generally available from chain pharmacies, such as charge accounts and deliveries to the elderly.

In November 1990, a detective with the Narcotics Bureau of the Columbus, Ohio Police Department conducted a routine inspection of Respondent pharmacy and its exempt narcotics log book. Under both Federal and state law a prescription is not required to purchase certain Schedule V cough syrups, however a log book must be maintain containing the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of purchase, and the name of the dispensing pharmacist. In addition, there is a limit on the amount of cough syrup that may be purchased by an individual within a 48 hour period. The inspection revealed that on 11 occasions, between February 1989 and November 1990, individuals had purchased Schedule V exempt narcotic cough syrups from Respondent more than once in a 48 hour period in violation of both Federal and state law. Further examination of Respondent's exempt narcotic log book revealed that certain individuals bought exempt narcotics from Respondent frequently and over an extended period of time. Specifically, between February 20, 1989 and November 18, 1990, an individual purchased exempt narcotics from Respondent on 126 occasions; between March 24, 1989 and February 7, 1990, an individual purchased exempt narcotics from Respondent on 63 occasions; another individual purchased exempt narcotics from Respondent on 97 occasions between January 2, 1989 and February 3, 1991; between January 15, 1989 and December 29, 1990, an individual purchased exempt narcotics from Respondent on 104 occasion; an individual purchased exempt narcotics on 87 occasions between January 16, 1989 and February 10, 1991; and another individual purchased exempt narcotics from Respondent on 34 occasions between August 25, 1990 and February 2, 1991.

The detective interviewed three of these individuals who all admitted purchasing exempt narcotics from Respondent. One stated that when he went to Respondent, there would be a bottle of cough syrup waiting for him by the time he reached the pharmacy counter. Another individual admitted to signing the log book using different names.

On January 30, 1991, the detective interviewed Jon Martin, Respondent's owner and pharmacist, and asked him how long it would take someone to become addicted to codeine if he/she drank a bottle of cough syrup every day or every other day. Mr. Martin stated that in his opinion it would take approximately 60 days. The detective then asked Mr. Martin why he continued to sell cough syrup to the same individuals. Mr. Martin replied that as long as customers stayed within the 48 hour rule, he would sell the cough syrup to them because if he did not, they would just buy it elsewhere. Mr. Martin went on to state that the pharmacy business is a tough business and he might as well make money.

In April 1991, the Columbus Police Department informed DEA of the results of its investigation of Respondent. DEA compared the amount of exempt narcotics sold by Respondent with the amount sold by the other five pharmacies located in Gahanna, Ohio, and discovered that during an average month in 1991, Respondent sold twice the quantity of exempt narcotic products as all the other local pharmacies combined. On April 18, 1991, DEA went to Respondent pharmacy to evaluate its compliance with the Controlled Substances Act. It was discovered that Respondent did not have a biennial inventory as required by Federal regulations. At the hearing before Judge Bittner, when asked about this Respondent stated that, ''I suspect it was just a matter of being a little lax on getting things done. It was nothing intentional. There's a lot of things for me to do. * * * Some of them are nit-picky things I neglected doing. I'm sorry.'' The DEA investigators also discovered that Respondent could not account for 18 of the 126 Schedule II order forms that it had been issued by DEA between January 1989 and April 1991. Respondent testified at the hearing before Judge Bittner that he was surprised that the order forms were missing, and that ''paperwork has not always been one of (his) strong suits.''

As part of its investigation, DEA conducted an accountability audit at Respondent pharmacy of eight controlled substances. The audit revealed both overages and shortages of all but one of the audited substances. For example, Respondent pharmacy could account for 164 tablets of Dilaudid 2 mg. (a Schedule II controlled substances) more than it was accountable, and could not account for 1,160 tablets of APAP with codeine (a Schedule III controlled substance) for

which it was accountable. At the hearing before Judge Bittner, Mr. Martin stated that had he been informed of the shortages at the time of the investigation, he probably could have accounted for the shortages. However, both the DEA investigator that testified at the hearing and Mr. Martin testified that at the time of the accountability audit, the investigator asked Mr. Martin several times if he had given or shown the investigator all of the pharmacy's controlled substances and records.

The DEA investigator returned to Respondent pharmacy on April 25, 1991, to verify refill information, and discovered that Respondent's records did not indicate dates of refills or verification by the dispensing pharmacist. The investigator also discovered that Respondent's records of oral prescriptions did not include information required by Federal regulations. The investigator seized seven controlled substance prescriptions issued to an individualy purportedly by one doctor. On April 30, 1991, the investigator met with the doctor who advised the investigator that he had not authorized one of the prescriptions at all and that another prescription that he had issued had been refilled five times, when he had only authorized one refill.

As a result of the investigation by the Columbus Police Department, the Ohio State Board of Pharmacy (Board) found that on nine occasions between March 1989 and November 1990, Mr. Martin had violated the 48 hour rule regarding the dispensing of exempt narcotics, and that he had sold codeine cough syrup for other than a legitimate medical purpose. The Board concluded that Mr. Martin was guilty of gross immorality, dishonesty and unprofessional conduct in the practice of pharmacy, and on August 11, 1992, suspended his license to practice pharmacy for one year, fined him $5,000.00, but permitted the pharmacy to continue operating without restriction.

Mr. Martin pled guilty in the United States District Court for the Southern District of Ohio to one misdemeanor count of unlawful distribution of a codeine-based exempt narcotic, and in September 1993, he was placed on probation for one year, fined $2,500.00 and ordered to perform 50 hours of community service. Mr. Martin paid the fine, but was excused from performing some of the community service, and his probation was terminated early.

Both the Columbus detective and the DEA investigator testified at the hearing in this matter that they have not received any complaints regarding Respondent's controlled substance dispensing since the investigation in 1991. Mr. Martin testified at the hearing that he assumes full responsibility for what happened at Respondent pharmacy, and that he has instituted procedural changes so nothing like it will happen again. The pharmacy no longer sells exempt narcotics without a prescription even though a prescription is not required by Federal or state law. Mr. Martin has hired a pharmacist to be responsible for all controlled substance inventories, Schedule II order forms, and other DEA requirements. It is now the pharmacy's policy to call prescribing doctors to verify refill information, and to note that information on the prescription and in the computer.

However, Mr. Martin admitted at the hearing that he was aware that certain individuals came to his pharmacy to buy Schedule V cough syrup because he always sold it to them. When asked why the pharmacy stopped selling exempt narcotics without a prescription, Mr. Martin testified, ''it's cost me a lot of money and a lot of time and a lot of anguish in my life that I really don't need. And besides that, I certainly wasn't helping the people.''

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending applications, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered:

(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 be denied. See *Henry J. Schwarz, Jr., M.D.,* Docket No. 88–42, 54 FR 16,422 (1989). In this case, factors one, two, three and four are relevant in determining the public interest.

As to factor one, ''recommendation of the appropriate licensing board * * *'' in 1992, the Ohio State Board of Pharmacy found that Mr. Martin had dispensed coedine cough syrup for no legitimate medical purpose and in violation of the prohibition against dispensing more than once in a 48 hour period to the same individual. As a result, the Board suspended Mr. Martin's license to practice pharmacy for one year. Mr. Martin's license to practice pharmacy and Respondent's license are currently unrestricted. While it is relevant that Respondent and its owner possess unrestricted state authorization to handle controlled substances, the Acting Deputy Administrator does not find it dispositive of whether Respondent's continued registration is in the public interest.

As to factor two, the Respondent's ''experience in dispensing * * * controlled substances,'' the Acting Deputy Administrator concurs with the Administrative Law Judge that ''this factor strongly weighs in favor of finding that Respondent's registration would not be in the public interest.'' In the case of Schedule V exempt narcotic cough syrups dispensed without a prescription, the responsibility to ensure that these substances are dispensed for a legitimate medical purpose rests solely with the pharmacist. See *Arthur Sklar, R.Ph., d/b/a/ King Pharmacy,* 54 FR 34,623 (1989). The Ohio State Board of Pharmacy found that Mr. Martin dispensed exempt narcotics to certain individuals for no legitimate medical purpose. Mr. Martin admitted that he was aware that certain individuals came to his pharmacy to buy Schedule V cough syrup for no legitimate medical purpose, because he always sold it to them. He stated that if he didn't sell it to them, they'd just go buy it elsewhere. He violated the prohibitions against dispensing exempt narcotics to the same individual more than once in a 48 hour period. It was Mr. Martin's opinion that an individual who took Schedule V cough syrup every day or every other day, could become addicted within 60 days, yet he continued to dispense these substances to individuals on a regular basis over several years. The Acting Deputy Administrator agrees with Judge Bittner's finding that ''Mr. Martin abrogated his professional and legal responsibilities with respect to dispensing controlled substances.''

Regarding factor three, it is uncontested that in September 1993, Mr. Martin pled guilty in the United States District Court for the Southern District of Ohio to one misdemeanor count of unlawful distribution of a codeine-based exempt narcotic, and he

was placed on probation for one year, fined $2,500.00 and ordered to perform 50 hours of community service.

As to factor four, the Respondent's ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances,'' the evidence presented at the hearing in this matter clearly supports the conclusion that Respondent committed numerous violations of applicable laws and regulations. Respondent failed to maintain complete and accurate records of its controlled substances as required by 21 U.S.C. 827 and 21 CFR 1304.21, as evidenced by the results of the accountability audit. Respondent failed to conduct a biennial inventory of its controlled substances as required by 21 CFR 1304.13. Pursuant to 21 CFR 1305.13, Respondent was required to preserve all Schedule II order forms. Its inability to account for 18 of its order forms indicates a violation of this regulation.

Respondent's maintenance of records regarding oral prescriptions and prescriptions refills was also deficient. Under 21 CFR 1306.21, a pharmacist may dispense a Schedule III or IV controlled substance pursuant to an oral prescription that is promptly reduced to writing by the pharmacist. The writing must contain all of the information required for a written prescription, including the date of issuance, the name and address of patient, and the name, address, and registration number of the prescribing practitioner. Respondent's oral prescription information failed to include the name and address of both the patient and the practitioner. Respondent's prescription refill records failed to include the date of the refill or verification information by the dispensing pharmacist, in violation of 21 CFR 1306.22(b) (1) and (3).

Respondent violated Section 3719.16 of the Ohio Revised Code and 21 CFR 1306.32 by selling codeine cough syrup on 11 occasions to the same individual more than once within a 48 hour period.

Of considerable concern to the Acting Deputy Administrator is Respondent's violation of 21 CFR 1306.04(a), which provides that:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription * * *

Accordingly, in situations where a prescription for a controlled substance is issued, both the prescribing practitioner and the dispensing pharmacist have the responsibility to ensure that the substances are being dispensed for a legitimate medical purpose. In this case, however, there is no prescribing practitioner. Therefore, the dispensing pharmacist bears the sole responsibility for evaluating the purpose and necessity for the dispensing of controlled substances. Mr. Martin himself admits that he ignored his responsibilities and dispensed the Schedule V cough syrups for no legitimate medical purpose. He attempted to justify his behavior by stating that if he did not sell the cough syrup, the customers would just go elsewhere. His only concern was to make money. Based upon these numerous violations of Federal and state laws and regulations relating to the dispensing of controlled substances, factor four is extremely significant in evaluating the public interest in this case.

Like Judge Bittner, the Acting Deputy Administrator notes Mr. Martin's testimony regarding the procedural changes that he has instituted to ensure that Respondent would comply with applicable laws and regulations in the future. However, he has delegated most of the responsibility concerning compliance to a pharmacist at Respondent. As the owner of Respondent, Mr. Martin is ultimately responsible for compliance, and by his own admission, he has not spent much time at Respondent recently.

The Acting Deputy Administrator concludes that regardless of whether Mr. Martin is present at the pharmacy or not, Respondent's continued registration is inconsistent with the public interest. Judge Bittner found that ''Mr. Martin displayed a total disregard for federal and State laws and regulations, and for his responsibilities as a licensed pharmacist and owner of a DEA registrant.'' The Acting Deputy administrator concurs with Judge Bittner's assertion that ''Mr. Martin testified that he accepted responsibility for his misconduct and recognized that he used poor judgment; however, his expression of regret was directed more to the consequences to himself of his action—the aggravation and loss of time and money—than to the conduct itself.'' Mr. Martin turned a blind eye to his duty as a DEA registrant to ensure that controlled substances were dispensed for a legitimate medical purpose. He characterized many of the registration requirements as ''nit-picky things.'' Those requirements are in place to guard against the diversion of controlled substances. To minimize these requirements demonstrates a lack of appreciation for the responsibilities of a DEA registrant. Consequently, the Acting Deputy administrator concludes that Respondent's continued registration is inconsistent with the public interest.

Accordingly, the Acting 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 DEA Certificate of Registration BR1448655, issued to Roger Pharmacy, be, and it hereby is revoked and any pending applications for renewal of such registration, be, and they hereby are, denied. This order is effective January 9, 1997.

Dated: December 2, 1996.

James S. Milford,

*Acting Deputy Administrator.*

[FR Doc. 96–31253 Filed 12–9–96; 8:45 am]

**BILLING CODE 4410–09–M**

## Immigration and Naturalization Service

### Agency Information Collection Activities: Extension of Existing Collection; Comment Request

**AGENCY:** Notice of information collection under review; application for waiver of ground of excludability.

Office of Management and Budget approval is being sought for the information collection listed below. This proposed information collection was previously published in the Federal Register on August 23, 1996, at 61 FR 43561, allowing for a 60-day public comment period. No comments were received by the Immigration and Naturalization Service.

The purpose of this notice is to allow an additional 30 days for public comments until January 9, 1997. This process is conducted in accordance with 5 CFR Part 1320.10.

Written comments and/or suggestions regarding the item contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, Attention: Department of Justice Desk Office, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 514–1534.