consultation between the AML agency and the appropriate Title V regulatory authority on the likelihood of removing the coal under a Title V permit and concurrences between the AML agency and the appropriate Title V regulatory authority on the AML project boundary and the amount of coal that would be extracted under the AML reclamation project.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: 26 State regulatory authorities and Indian tribes.

Total Annual Responses: 45.

Total Annual Burden Hours: 3,240.

Dated: March 19, 2001.

Richard G. Bryson,

Chief, Division of Regulatory Support.

[FR Doc. 01–8431 Filed 4–5–01; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[USITC SE–01–013]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: April 16, 2001 at 11 a.m.

PLACE: Room 101, 500 E Street S.W., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meeting: none.
2. Minutes.
3. Ratification List.
4. Inv. No. 731–TA–922 (Preliminary)(Automotive Replacement Glass Windshields from China)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on April 16, 2001; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on April 23, 2001.)
5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: April 4, 2001.

By order of the Commission:

Donna R. Koehnke,

Secretary.

[FR Doc. 01–8649 Filed 4–4–01; 1:14 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 99–13]

Alexander Drug Company, Inc.; Revocation of Registration

The Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause, dated January 22, 1999, to Alexander Drug, Co., Inc. (Respondent), seeking to revoke its DEA Certificate of Registration, #BA2660214, and deny any applications for renewal of such registration pursuant to 21 U.S.C. 824(a)(2) for the reason that the Respondent was convicted of a felony related to controlled substances, and section 824(a)(4) for the reason that the Respondent's continued registration would be inconsistent with the public interest, as defined in 21 U.S.C. 823(f). The Order to Show Cause alleged that these grounds were evidenced by the following:

1. The Respondent pharmacy had violated several state regulations and laws regarding record keeping.
2. A pharmacist employee of the Respondent dispensed a controlled substance on two occasions without a physician's authorization.
3. A DEA inspection on August 6, 1996, revealed over one-thousand record keeping violations.
4. On April 28, 1997, the Respondent pharmacy and the president of the Respondent pharmacy were indicted on sixteen felony counts of maintaining false records and one count of conspiracy.
5. On July 28, 1997, the Respondent pharmacy was convicted, upon a plea of guilty, of a felony related to maintaining false records.
6. The president of the Respondent pharmacy was indicted and convicted upon a plea of guilty of one felony count of obstructing a federal officer.
7. The president of the Respondent pharmacy was indicted on three felony counts of making a misrepresentation in the filing of insurance billing.
8. On December 22, 1997, a pharmacist employee of the Respondent was charged with one felony count of obtaining controlled substances under false pretenses and one felony count of conspiracy to obtain controlled substances by fraud.

The Respondent timely filed a request for a hearing on the allegations raised by the Order to Show Cause. After granting the Respondent's emergency motion for a continuance on June 7, 1999, the requested hearing was held in Greenville, South Carolina, on August 17, 1999, before Administrative Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed Proposed Findings of Fact, Conclusions of Law Argument. On March 22, 2000, Judge Randall issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Opinion). On May 17, 2000, the record of these proceedings was transmitted to the Administrator for final decision.

The Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon the findings of fact and conclusions of law as hereinafter set forth. The Administrator adopts the findings of fact as set forth in Judge Randall's Opinion and also adopts Judge Randall's recommended conclusions of law and decision.

The issue in this proceeding is whether or not the record as a whole establishes a by a preponderance of the evidence that the DEA should revoke the DEA Certificate of Registration of Alexander Drug Co., pursuant to 21 U.S.C. 824(a)(2) and 824(a)(4), and should deny any pending applications for renewal of such registration as a retail pharmacy pursuant to 21 U.S.C. 823(f), because Alexander Drug Co. was convicted of a felony and an officer of Alexander Drug Co. was convicted of a misdemeanor arising out of this investigation but not related to controlled substances, and because the continued registration of Alexander Drug Co. would be inconsistent with the public interest.

The Administrator finds as follows: The Respondent is located in Greenville, South Carolina, and holds a DEA Certificate of Registration, BA2660214, as a retail pharmacy. The Respondent timely submitted a renewal application for this registration, that remains pending before the DEA. Mark Wansley is the President, owner, and pharmacist in charge of Respondent pharmacy. Sam Gaillard began working in charge of Respondent pharmacy. Sam Gaillard began working as a pharmacist for the Respondent in 1955. In 1957, he purchased the Respondent. In 1991, he sold the Respondent to Mr. Wansley but continued to be employed by the Respondent as a pharmacist until 1998.

On July 20, 1994, two inspectors of the South Carolina Department of Health and Environmental Control (DHEC) conducted a routine inspection of the Respondent's controlled substance dispensing records. The inspectors noted their findings on a

Pharmacy Inspection Form. The Pharmacy Inspection Form contains a list of areas reviewed during a South Carolina State pharmacy inspection. An inspector testified that during an inspection, the inspector may write an S (satisfactory), I (improvement needed), or U (Unsatisfactory) next to any general area of review. These notations are meant to heighten the awareness of the pharmacist to the pharmacy's practices in these areas. The determination of which notation a pharmacy receives depends on the number of violations found under the area of review. This DHEC inspection was the first of three such inspections, as set forth below, and a DHEC inspector who participated in each of the three inspections testified as to the findings of each inspection. Judge Randall credited the testimony of the DHEC inspector with regard to the findings of each of the inspections, as set forth below.

The DHEC inspectors found that the Respondent's dispensing records for Schedule II controlled substance transfers included locally prepared prescription forms rather than the required DEA Form 222. The DHEC inspectors advised Mr. Wansley to use DEA form 222 for future controlled substance transfers, but the inspectors did not mark this area of review with an unsatisfactory designation.

The DHEC inspectors noted on the Pharmacy Inspection Form that the dispensing records did not clearly state specific directions with regard to each controlled substance dispensed. The applicable Pharmacy Inspection Form indicates that the Respondent's practices in this area were satisfactory, however. Judge Randall credited the inspector's testimony that noting a potential discrepancy in this area is a ''means of trying to heighten the pharmacist's awareness to try to document according to the regulations.''

The DHEC inspectors found two prescriptions for controlled substances that did not contain a physician's signature. The inspectors indicated on the Pharmacy Inspection Form that the Respondent needed to improve its record keeping in this area.

The DHEC inspectors also informed the respondent of several repeat sales of Schedule V controlled substances to five individuals. State law requires documentation of such sales in a specified manner, including a description of why repetitive sales were needed.

The DHEC inspector testified that the respondent had failed to note the reason that repetitive sales were allowed. The inspectors indicated on the Pharmacy Inspection Form that the Respondent needed to improve its record keeping in this area.

On August 24, 1995, two DHEC inspectors conducted a second inspection of the Respondent. Mark Wansley was present during the inspection. The inspectors noted their findings on a Pharmacy Inspection Form.

The DHEC inspectors noted that the Respondent had failed to record the dates when shipments of controlled substances were received at the pharmacy. The inspectors indicated on the Pharmacy Inspection Form that the Respondent needed to improve its record keeping in this area.

The DHEC inspectors found that, due to a problem with the Respondent's computer system, some dispensing records for controlled substances did not contain complete patient addresses. Additionally, the inspectors noted that some of the dispensing records did not properly contain the dispensing pharmacist's information. The inspectors indicated on the Pharmacy Inspection Form that the Respondent needed to improve its record keeping in these area. The inspectors found more violations in these areas than could be recorded on the Pharmacy Inspection Form.

As was found during the July 20, 1994 inspection, the DHEC inspectors again noted that the respondent's records for Schedule II controlled substance transfers included locally prepared prescription forms rather than the required DEA form 222. The inspectors indicated on the Pharmacy Inspection Form that the Respondent needed to improve its record keeping in this area.

The DHEC inspectors noted several post-dated prescriptions, where the dispensing records indicated that prescriptions for controlled substances were written after the date that the Respondent filled the prescriptions. The inspectors also noted that at least one prescription refill was filled improperly more than 30 days after it was written by the practitioner.

As was noted during the July 20, 1994 inspection, the DHEC inspectors found several repeat sales of Schedule V controlled substances and informed the Respondent ''to be careful.''

On April 19, 1996, DHEC inspectors conducted a third inspection and also an audit of the Respondent. The inspectors noted their findings on a Pharmacy Inspection Form.

The DHEC inspectors again found that the Respondent had transferred Schedule II controlled substances to another registered party without maintaining the proper records, including a DEA Form 222. The records on file for such transfers were unsatisfactory as they did not properly indicate the dates of the transfers. The unsatisfactory condition of these records was noted on the Pharmacy Inspection Form.

The DHEC inspectors again found prescriptions without the proper patient or practitioner name and address information. The inspectors also found several controlled substance prescriptions that were expired or out of date; prescriptions for controlled substances that contained ''use as directed'' instructions rather than more specific dosage directions; dosages dispensed with directions that indicate the amount dispensed exceeded the maximum 30-day limit for the substance; refills that were filled early; one prescription that appeared to be filled with the incorrect controlled substance; and a phone-in prescription for a Schedule II controlled substance that exceeded the amount allowable for an emergency situation. The investigator testified that each of these practices is a violation of state regulation.

As was noted during the previous two inspections, the DHEC inspectors found several repeat sales of Schedule V controlled substances that did not contain the proper state-required documentation.

During this inspection, the DHEC inspectors conducted an inventory and audit of six selected controlled substances. The inspectors analyzed the inventory records, invoices, transfer documents, and dispensing records related to th4ese substances from May 1, 1995, to April 19, 1996, and compared the recorded data to the amounts of the substances in inventory on April 19, 1996. The inspectors found the following shortages or overages for each substance:

Adderall: shortage of 41 dosage units
alprazolam: overage of 1,743 dosage units
Android: overage of 30 dosage units
Bontril: overage of 799 dosage units
Fiorinal: shortage of 27 dosage units
oxycodone: shortage of 176 dosage units

The inspector testified that the series of DHEC inspections showed a consistent pattern of noncompliance with state regulation.

During the April 19, 1996 inspection, the DHEC inspectors also discovered that the Respondent's records contained the following falsified phone-in prescriptions for controlled substances which had been illegally dispensed.

In 1995, Sam Gaillard injured his back, which caused him discomfort. Mr. Gaillard was told by his physician to contact him whenever he needed

medication for pain. On at least ten occasions, Sam Gaillard was unable to reach his treating physician. In order to treat his back pain, Sam Gaillard wrote several controlled substances prescriptions for himself using his physician's name and dispensed the controlled substances to himself. Each prescription identifies Sam Gaillard as the recipient of these medications.

On or about September 29, 1995, and again on or about November 3, 1995, Sam Gaillard dispensed Lorazepam, a Schedule IV controlled substance, to himself, in the name of his wife, without a prescription issued by a practitioner in the usual course of professional practice. He also created a false prescription record indicating that a physician had authorized the prescription. Mr. Gaillard created this false prescription in the name of his wife because her health insurance did not require co-payment.

On or about December 22, 1995, the pharmacy records indicate that Mark Wansley dispensed Lorazepam, a Schedule IV controlled substance, to Sam Gaillard without a prescription issued by a practitioner in the usual course of professional practice and that he created a false prescription record indicting that a physician had authorized the prescription. Although Mark Wansley's initials appear on the record for this prescription, Sam Gaillard testified that he was responsible for filling this prescription and creating the false record. Judge Randall credited Sam Gaillard's testimony that the Respondent's closing procedures often include the evening pharmacist initialing prescriptions that had been filled earlier in the day, in explaining how Mark Wansley's initials could appear on a prescription filled by Sam Gaillard. Judge Randall also credited the testimony of a DEA Diversion Investigator who testified, however, that Sam Gaillard stated to him that Mark Wansley knew of Gaillard's illicit activities. On or about January 24, 1996, and March 29, 1996, Sam Gaillard refilled this prescription and created a false prescription record indicating that a physician had authorized the refills.

Again, on or about February 1, 1996, Sam Gaillard dispensed Vicodin, a Schedule III controlled substance, to himself, without a prescription issued by a practitioner in the usual course of professional practice. Yet Sam Gaillard created a false prescription record indicating that a physician had authorized the prescription.

Sam Gaillard also took a medication prescribed for his wife and found that it relieved his back spasms. On or about March 5, 1996, Sam Gaillard then dispensed hydrocodone, a Schedule III controlled substance, to himself, in the name of this wife, without a prescription issued by a practitioner in the usual course of professional practice. He created a false prescription record indicating that a physician had authorized the prescription.

On or about February 1, 1996, and again on or about February 6, 1996, Sam Gaillard dispensed QV Tussin, a Schedule V controlled substance, to himself, in the name of his wife, without a prescription issued by a practitioner in the usual course of professional practice. He also created a false prescription record indicating that a physician had authorized the prescription.

Sam Gaillard's son suffers from migraine headaches and had been prescribed Fiorinal #3 by his treating physician. When he was unable to reach his son's physician, Sam Gaillard wrote a prescription for Fiorinal #3 using the name of his son's treating physician and dispensed the controlled substances to his son.

On five separate occasions on or about November 23, 1994, May 26, 1995, September 19, 1995, December 12, 1995, and February 23, 1996, Sam Gaillard dispensed Fiorinal #3, a Schedule III controlled substance, to his son, without a prescription issued by a practitioner in the usual course of professional practice. He also created a false prescription record indicating that a physician had authorized the prescription.

On or about December 18, 1995, Sam Gaillard dispensed Prometh VC with codeine, a Schedule V controlled substance, to his son, without a prescription issued by a practitioner in the usual course of professional practice. He also created a false prescription record indicating that a physician had authorized the prescription.

On or about April 12, 1996, at Sam Gaillard's request, Mark Wansley dispensed Fiorinal #3, a Schedule III controlled substance, to Sam Gaillard's son without a prescription issued by a practitioner in the usual course of professional practice. He also created a false prescription record indicating that a physician had authorized the prescription. Judge Randall credited Sam Gaillard's testimony that he told Mark Wansley that he would obtain proper authorization from his son's physician, but he never did so.

Sam Gaillard was charged in Greenville County, South Carolina, with obtaining controlled substances by fraud, and entered a pre-trial intervention program. In accordance with S.C. Code Ann. section 17–22–150, a successful completion of this program results in a non-criminal disposition of the charges.

On August 6, 1996, DEA Diversion Investigators executed a search warrant and conducted an inspection of the Respondent. During the execution of the warrant, the investigators acquired copies of DEA 222 Narcotic Order Forms, invoices for the purchase of controlled substances, prescriptions for controlled substances, and records for the purchase, sale, and transfer of listed chemicals. Judge Randall credited the testimony of a DEA Diversion Investigator (Investigator) with regard to the findings of this investigation.

The Investigator testified that on thirteen occasions, the Respondent transferred Schedule II controlled substances to other DEA registrants without properly executing a DEA Form 222. Although the Respondent did not prepare a DEA Form 222 for any of these transfers as required, the Respondent maintained records indicating the quantity and locations of controlled substances transferred. The Investigator testified that had the information contained on these records been placed properly on DEA forms, there would have been no violation.

The Investigator also testified that the Respondent transferred Schedule III through V controlled substances on nine occasions without recording the proper information, including names, dates, substance type, and quantity. The Respondent did maintain records of each transfer. The records did not always contain all of the required information, however, and they were not always correctly maintained in the Respondent's filing system.

The Investigator further testified that, between April of 1994 and July of 1996, on thirty occasions the Respondent failed to complete properly the required Supplier's Copy 1 of DEA Form 222. The Supplier's Copy 1 of DEA Form 222 failed to include the supplier's DEA number and street address. Further, on fifty occasions between August 23, 1994, and July 19, 1996, the Respondent failed to complete properly the required Purchaser's Copy 3 of DEA Form 222. Many of the records for these transfers were attached to invoices that contained a description of the type of controlled substance transferred, the quantity transferred, and the location of the transfer, however. Thus, the Respondent had the required information, but had failed to record completely the information on the required forms.

On approximately 1000 occasions between August 1994 and August 1996,

the Respondent failed to record information on purchase invoices for controlled substances as required by federal regulations. Missing information included the date the shipment of controlled substances was received, improperly recorded addresses, and no entry showing the number of packages actually received. This information is significant, the pharmacy needs the date and the quantity received to properly account for the controlled substances on hand and subsequently dispensed.

Between November 17, 1995, and July 16, 1996, the Respondent purchased approximately 36,000 capsules of the List I chemical ephedrine without maintaining any required sales records. Regulations involving the record keeping requirements for the purchase and sale of ephedrine were changed in 1994; yet the Respondent's records were not in compliance with these requirements by 1995 or 1996.

During the execution of the search warrant, Mark Wansley was arrested by DEA agents for failing to follow law enforcement officers' instructions, and he was charged with interfering with Federal officers in the execution of a warrant. During the execution of the search warrant, Mr. Wansley chose to remain at the Respondent during the search. The DEA investigators told him to remain seated during the search. Subsequently, Mark Wansley's mother knocked on the back door of the Respondent, and a DEA agent instructed Mr. Wansley that he could not leave his seat to speak with his mother. Contrary to the instructions of the DEA agent, Mr. Wansley left his seat, resulting in his being arrested.

Subsequently, Mark Wansley was indicted, with one count pertaining to the obstruction of a federal officer during the execution of a search warrant in violation of 18 U.S.C. 111.

On July 28, 1997, in the United States District Court for the District of South Carolina, Mark Wansley pleaded guilty to a misdemeanor count of Assaulting, Resisting and Impeding an Agent of the United States in violation of 18 U.S.C. 111 and was sentenced to two years probation.

As a result of the DEA investigation, Mark Wansley and the Respondent were indicted on sixteen felony counts of maintaining false records in violation of 21 U.S.C. 843(a)(4)(A), and one count of conspiracy in violation of 21 U.S.C. 846. The government did not seek conviction on the conspiracy count.

On July 28, 1997, in the United States District Court for the District of South Carolina, the Respondent was convicted of one felony count of maintaining false records in violation of 21 U.S.C. 843(a)(4)(A) and was sentenced to two years of probation and fined $20,000.

Pursuant to 21 U.S.C. 824(a), ''A registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * (2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical.'' Pursuant to this statute, a felony conviction is an ''independent statutory basis for revocation of a registration.'' See Bobby Watts, M.D., 58 FR 46995 (DEA 1993) (providing the standard for finding an independent statutory basis for revocation under section 824(a)). While a conviction for a felony related to controlled substances creates a lawful basis to revoke a pharmacy's DEA Certificate of Registration under 21 U.S.C. 824(a)(2), it remains within the Administrator's discretion as to whether or not to revoke the registration. Dobson Drug Co., Inc., 56 FR 46445, 46446 (DEA 1991).

The record in this proceeding demonstrates that the Respondent was convicted of one felony count of maintaining false records regarding the dispensing of controlled substances in violation of 21 U.S.C. 843(a)(4)(A). Pursuant to 21 U.S.C. 843(a)(4)(A), it shall be unlawful ''to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter.'' Thus the preponderance of the evidence establishes this basis for revocation of the Respondent's Certificate of Registration.

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Administrator may revoke a DEA Certificate of Registration and deny any pending applications to renew that registration, if he determines that the continued registration would be inconsistent with the public interest. See KK Pharmacy, 64 FR 49507 (DEA 1999). 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 or safety.

It should be noted that these factors are to be considered in the disjunctive: the Administrator may properly rely on any one or a combination of these factors, and may give each factor the weight he deems appropriate in determining whether an application for registration should be denied. See Henry J. Schwarz, Jr., M.D., 54 FR 16,422 (DEA 1989).

Regarding factor one, in accordance with 21 U.S.C. 823(f)(1), the Administrator shall consider the recommendation of the appropriate state licensing agency in determining whether a registrant's continued registration is consistent with the public interest. Here, the state agency has not made a recommendation pertaining to the resolution of this proceeding.

Further, a valid state registration is a prerequisite for DEA Registration. See 21 U.S.C. 823(f) (authorizing the Attorney General to register a practitioner to dispense controlled substances only if the applicant is authorized to dispense controlled substances under the laws of the state in which he or she conducts business); 21 U.S.C. 802(21) (defining ''practitioner'' as ''a pharmacy * * * or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to distribute, [or] dispense * * * controlled substance[s] in the course of professional practice''). In this case, the Respondent maintains state authority to handle and distribute controlled substances in the State of South Carolina.

In accordance with 21 U.S.C. 823(f)(2), the Administrator shall consider the registrant's experience in dispensing controlled substances in determining whether its continued registration is consistent with the public interest. The Administrator shall also consider, pursuant to 21 U.S.C. 823(f)(4), the applicant's compliance with state and federal law. As the Respondent's experience in dispensing controlled substances is related to its compliance with state and federal law, factors two and four will be considered together. See Service Pharmacy, 61 FR 10,791, 10,795 (DEA 1996).

It is undisputed that the Respondent was convicted of the felony of maintaining false records regarding the dispensing of controlled substances in violation of 21 U.S.C. 843(a)(4)(A). Additionally, the DHEC investigators detailed a series of the Respondent's

record keeping discrepancies over a 21 month period, including failures to record required information on the required forms. Additionally, the DHEC investigators also noted that the Respondent failed properly to record repeat sales of Schedule V controlled substances as required by state regulation. The DHEC investigators noted that the majority of these discrepancies were in areas in which the Respondent needed to improve its practices. In three inspections of the Respondent, the DHEC investigators noted three areas in which the Respondent's practices were unsatisfactory. As was explained during the hearing in this matter by the testifying DHEC investigator, the notations on the Pharmacy Inspection Form generally were intended to help the Respondent understand and fully comply with the relevant state and federal regulations. The results of the DHEC investigation show that, although repeatedly advised of relevant state and federal regulations, the Respondent did not alter its practices to conform to these regulations. By not following the directives of the DHEC investigators, the Respondent's actions over the 21 month period show a general and continued noncompliance with state regulation.

Similarly, the DEA investigation revealed that the Respondent had committed a series of record keeping violations. By not properly preparing DEA Form 222 for each Schedule II transfer, and by not properly preparing Supplier's Copy 1 and Purchaser's Copy 3 of DEA Form 222 for each Schedule II transfer, the Respondent violated 21 U.S.C. 828 and 842(a)(5), and 21 CFR 1305.03, 1305.09, and 1305.11. Respondent also failed properly to record information on purchase invoices for controlled substances in violation of 21 U.S.C. 827 and 842(a)(5), and 21 CFR 1304.22. The non-conforming records actually on file with the Respondent arguably detailed sufficient information to determine that the controlled substances were not diverted to an illicit purpose, however, but were actually transferred to other registrants. Nevertheless, Respondent's non-conforming record keeping is also a violation of 21 CFR 1304.04.

Even if Respondent arguably had sufficient albeit non-conforming information in its files to comply with some of the state and federal record keeping requirements (Respondent had no records whatsoever regarding the disposition of the 36,000 capsules of the List I chemical ephedrine), this does not absolve Respondent from its obligation to adhere to the law. The efficacy of the closed system of distribution for controlled substances and certain chemicals mandated by Congress through the Controlled Substances Act depends upon strict adherence by all registrants to all record keeping requirements including those set forth at 21 U.S.C. 827, 828, 829, and 830, and all implementing regulations found in Title 21 Code of Federal Regulations, as well as all applicable state laws and regulations.

Past DEA cases consistently have held that the failure to comply with record keeping requirements is a basis for revoking a registration. Singers-Andreini Pharmacy, Inc., 63 FR 4,668 (DEA 1998); Arthur Sklar, d/b/a King Pharmacy, 54 FR 34623 (DEA 1989); Summer Grove Pharmacy, 54 FR 28522 (DEA 1989); The Boro Pharmacy and Bell Apothecary, 53 FR 15151 (DEA 1988). These cases reflect the Congressional purpose and intent embodied in the Controlled Substances Act with regard to protecting the public against the dangers of the diversion of controlled substances. ''In passing the Controlled Substances Act, 'Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels.' '' *United States* v. *Frederick M. Blanton,* 730 F.2d 1425, 1427, (11th Cir. 1984) (*quoting United States* v. *Moore,* 423 U.S. 122, 135, 96 S. Ct. 335, 342 (1975). ''The purpose of the enactment of the [Controlled Substances Act] was to provide a system for the control of drug traffic and to prevent the abuse of drugs. The statutory scheme envisioned by the Act is one of control through record keeping. Any person who desires to shoulder the responsibility of engaging in the manufacture or distribution of these products subjects himself to the regulatory system laid down by the 1970 act.'' *United States* v. *Stidham,* 938 F. Supp. 808, 814 (S.D. Ala. 1996) *quoting United States* v. *Greenberg,* 334 F. Supp. 364, 366–7, (W.D. Pa. 1971). ''The Controlled Substances Act attempts to limit this diversion by strict registration requirements of all persons . . . who are authorized by state law to handle controlled substances. The registration scheme includes formalized drug ordering procedures and certain types of recordkeeping thus allowing the federal government's Drug Enforcement Administration to closely monitor the flow of controlled substances from manufacturer to the hands of the consumer.'' *Blanton,* 730 F.2d at 1427. ''The Controlled Substances Act focuses on recordkeeping, in 'an attempt to regulate closely the distribution of certain substances determined by Congress to pose dangers, if freely available, to the public at large.' '' *United States* v. *David P. Poulin,* 926 F. Supp. 246, 250 (D. Mass. 1996) *quoting United States* v. *Averi,* 715 F. Supp. 1508, 1510 (M.D. Ala. 1989). The statutory text and legislative history of the Controlled Substances Act makes clear that Congress intended strict compliance with the recordkeeping provisions. *United States* v. *Green Drugs,* 905 F.2d 694, 698 (3d Cir. 1990), *cert. denied,* 498 U.S. 985, 111 S.Ct. 518 (1990); *United States* v. *James Little,* 59 F. Supp. 2d 177, 183 (D. Mass. 1999). *See also United States* v. *Naeem Akhtar,* 95 F. Supp. 2d 668, 671 (S.D. Tex. 1999); *United States* v. *Stidham,* 938 F. Supp. at 813.

The DHEC audit and inventory of the Respondent revealed shortages or overages of each controlled substances investigated. These discrepancies constitute a violation of 21 U.S.C. 827 and 21 CFR 1304.21, which require the Respondent to keep complete and accurate records of all controlled substances. The audit also revealed the presence of prescriptions that were post-dated, filled beyond the expiration date, incorrectly filled, refilled too early, and filled for more than allowed by regulation. These practices constituted a violation of state and federal regulations.

The DEA inspection also found that the Respondent purchased approximately 36,000 units of the List I chemical ephedrine without maintaining any required sales record, which is a violation of 21 U.S.C. 830(a) and 842(a)(10), and 21 CFR 1310.03 and 1310.04. As previously noted, the regulations regarding record keeping requirements for the purchase and sale of the List I chemical ephedrine were changed in 1994; yet the Respondent's records were still not in compliance with these requirements from November 1995 through July 1996. Therefore, the Administrator finds Respondent's consistent pattern of record keeping violations weigh in favor of revocation of its registration.

The DEA has consistently recognized that a pharmacy operates under the control of owners, stockholders, pharmacists, or other employees. Further, the DEA has consistently held that the conduct of these individuals is relevant in evaluating a respondent pharmacy's fitness to be registered by the DEA. See e.g., Rick's Pharmacy, 62 FR 42,595, 42,597 (DEA 1997); Big T Pharmacy, Inc., 47 FR 51,830 (DEA 1982), Seals Energy Outlet, 64 FR 14,269, 14,271 (DEA 1999). On fourteen occasions, the former owner and pharmacist-in-charge of the Respondent, Sam Gaillard, dispensed controlled

substances without practitioner authorization in violation of 21 U.S.C. 829 and 21 CFR 1306.11(a). These violations include the dispensing of twelve unauthorized prescriptions and the dispensing of two unauthorized refills. On at least one occasion the current owner and pharmacist-in-charge of the Respondent, Mark Wansley, dispensed controlled substances without practitioner authorization in violation 21 U.S.C. 829 and 21 CFR 1306.11(a). Additionally, a DEA Diversion Investigator credibly testified that Sam Gaillard stated that Mark Wansley knew about these illicit activities. For each unauthorized distribution of controlled substances, the Respondent's agents created a false record indicating that the distributions were authorized. This falsification of records is a violation of 21 U.S.C. 843(a)(4)(A).

Each of these prescriptions was dispensed to Sam Gaillard or a member of his family. Sam Gaillard is no longer employed by the Respondent, however. Therefore, these unauthorized distributions currently pose no threat to the public interest.

Regarding factor three, Respondent's conviction record, the record in this proceeding demonstrates without dispute that the Respondent was convicted of one felony count of maintaining false records regarding the dispensing of controlled substances in violation of 21 U.S.C. 843(A)(4)(A).

With regard to the fifth factor, such other conduct which may threaten the public health or safety, the record in this case demonstrates without dispute that Mark Wansley, owner and pharmacist-in-charge of the Respondent, was convicted of the offense of Assaulting, Resisting, and Impeding an Agent of the United States. While Mr. Wansley's failure to follow the specific instructions of a DEA agent are relevant to a determination under this factor, the Administrator concurs with Judge Randall's finding that the circumstances surrounding this arrest and conviction are also relevant. Mark Wansley's actions had no effect on the DEA's ability to seize the targeted records nor did his actions serve to hide evidence from the investigation.

Also relevant to this factor, the record demonstrates that Sam Gaillard created two false prescription records in his wife's name, and he used these prescriptions to make false representations to an insurance carrier. Again, however, also significant is the fact that Sam Gaillard is no longer employed by the Respondent.

Finally, past DEA cases have found record keeping violations to be a basis for the revocation of a registration based on the public interest. Summer Grove Pharmacy, 54 FR 28522 (DEA 1989).

The Administrator concurs with Judge Randall's conclusion that a preponderance of the evidence shows that the Respondent has violated state and federal law regarding the dispensing of controlled substances, and finds that the Respondent was convicted of a felony related to maintaining false records regarding the dispensing of controlled substances. Accordingly, the Administrator finds that the Government has established by a preponderance of the evidence that a basis exists to revoke the Respondent's DEA Certificate of Registration and to deny the pending renewal application. See Fourth Street Pharmacy, 52 FR 32,068 (DEA 1987) (holding that a conviction of the respondent corporate entity for a felony related to controlled substances is sufficient ground for revocation of a DEA Certificate of Registration).

In determining whether revocation is warranted, the Administrator looks to the totality of the circumstances in each case. Martha Hernandez, M.D., 62 FR 61,145 (DEA 1997). The record demonstrates that the Respondent has taken proper ameliorative action by no longer employing Sam Gaillard. However, the DHEC and DEA inspections together revealed a consistent pattern of numerous state and federal record keeping violations spanning a period of over two years. The Administrator concurs with Judge Randall's concern that the Respondent presented no evidence demonstrating a change in record keeping practices. See Singers-Andreini Pharmacy, Inc., 63 FR 4,668, 4,6672 (DEA 1998). Mark Wansley's silence leaves the record void of any assurances of his future accountable conduct. See AML Corp., 61 FR 8,973, 8,976 (DEA 1996) (finding that the pharmacy owner's failure to acknowledge past misconduct is significant in determining the public interest). Furthermore, past DEA cases have found that a negative inference may be drawn from a respondent's silence. Alan L. Ager, D.P.M., 63 FR 54,732 (DEA 1998).

The actions by the Respondent's employees in creating false records are significant. The Administrator concurs with Judge Randall's finding that the evidence credibly shows Mark Wansley dispensed controlled substances on at least one occasion without practitioner authorization, and created at least one false prescription record. Such an indication of willingness to engage in dishonest conduct weights heavily in favor of revocation, especially since the record contains no assurances that such conduct will not be repeated in the future. See Rocco's Pharmacy, 62 FR 3,056 (DEA 1997) (holding that improper dispensing of controlled substances is significant in predicting future compliance with relevant regulations).

The DHEC audit of controlled substances revealed overages and shortages, indications that the Respondent's record keeping practices are not adequate to account for the controlled substances handled by the Respondent's employees. These overages and shortages demonstrate that Respondent's record keeping practices do not comport with the legal requirements and present an unacceptable risk of diversion. Further, the Respondent purchased approximately 36,000 units of a List I chemical, yet failed to account for any of its distribution. Thus no records exist to assure the DEA that this substance was lawfully distributed, in violation of 21 U.S.C. 830(a) and 842(a)(10), and 21 CFR 1310.03 and 1310.04.

After reviewing the totality of the circumstances, the Administrator finds that revocation is warranted in this case. The Administrator is very concerned regarding the absence of evidence of remedial actions and the Respondent's demonstrated continued unwillingness or inability to comply with state and federal regulations in the recording and handling of controlled substances and List I chemicals. See Singers-Andreini Pharmacy, Inc., 63 FR 4,668 (DEA 1998); AML Corp., 61 FR 8,973 (DEA 1996). Respondent's failure to comply with relevant record keeping requirements creates a serious risk of diversion, specifically undetected diversion. Such a risk is inconsistent with the public interest. The three DHEC inspections and the subsequent DEA inspection of the Respondent together revealed a persistent pattern of non-compliance with applicable record keeping regulations spanning over two years. Since ''an agency rationally may conclude that past performance is the best predictor of future performance,'' *Alra* v. *Drug Enforcement Administration,* 54 F.3d 450 (7th Cir. 1995), the Administrator concludes that this persistent pattern of non-compliance, taken together with Mark Wansley's failure to testify as to corrective actions taken to prevent future record keeping violations, create an unacceptable risk for the public interest. It is the Respondent's responsibility to conduct its business in a manner that does not place the public at risk for the diversion of controlled substances.

Accordingly, the 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 BA2660214, issued to Alexander Drug Co., Inc., be, and it hereby is, revoked. The Administrator further orders that any pending applications for the renewal of such registration, be, and they hereby are, denied. This order is effective May 7, 2001.

Dated: March 27, 2001.

Donnie R. Marshall,

Administrator.

[FR Doc. 01–8478 Filed 4–5–01; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on December 3, 2000, Ansys Technologies, Inc., 25200 Commercentre Drive, Lake Forest, California 92630, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Phencyclidine (7471)	II
1-Piperidinocyclohexane carbonitrile (PCC) (8603).	II
Benzoylecgonine (9180)	II

The firm plans to manufacture the listed controlled substances to produce standards and controls for in-vitro diagnostic drug testing systems.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than June 5, 2001.

Dated: March 29, 2001.

Laura M. Nagel,

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

[FR Doc. 01–8550 Filed 4–5–01; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated September 28, 2000, and published in the **Federal Register** on October 18, 2000, (65 FR 60976), B.I. Chemicals, Inc., 2820 No. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Amphetamine (1101)	II
Methadone (9250)	II
Methadone-intermediate (9254)	II
Levo-alphacetylmethadol (9648)	II

The firms plans to bulk manufacture the listed controlled substances.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of B.I. Chemicals, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated the firm on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, 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 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 the basic classes of controlled substances listed above is granted.

Dated: March 29, 2001.

Laura M. Nagel,

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

[FR Doc. 01–8548 Filed 4–5–01; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 99–30]

Barry H. Brooks, M.D.; Continuation of Registration

On April 8, 1999, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Barry H. Brooks, M.D. (Respondent), of Cleveland, Ohio, proposing to revoke his DEA Certificate of Registration BB2048127, pursuant to 21 U.S.C. 824(a)(1), (2), and (4), and to deny any pending applications for such registration pursuant to 21 U.S.C. 823(f).

Respondent timely requested a hearing on the issues raised by the Order to Show Cause, and following pre-hearing procedures, a hearing was held in Cleveland, Ohio, on December 7, 1999, before Administrative Law Judge Mary Ellen Bittner. At the hearing, both parties called witnesses and introduced documentary evidence. After the hearing, the Government submitted proposed findings of fact, conclusions of law, and argument; and Respondent submitted a ''Post Hearing Brief.'' On May 24, 2000, Judge Bittner issued her Opinion and Recommended Decision, recommending that the Respondent's registration be continued, and that any pending applications for renewal be granted. On July 18, 2000, Judge Bittner transmitted the record of these proceedings to the Administrator for his final order.

The Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order adopting the Opinion and Recommended Decision of the Administrative Law Judge. His adoption is in no matter diminished by any recitation of facts, issues, and conclusions herein, or by any failure to mention a matter of fact or law.

The Administrator finds that the Respondent graduated from Harvard Medical School in 1967 and thereafter completed training in psychiatry and internal medicine. Since 1979, he has been a member of the faculty at Case Western Reserve University School of Medicine, and he is currently on the staff at five hospitals, while maintaining a private practice in Cleveland, Ohio. Respondent is a recovering alcoholic who is actively involved in Alcoholics Anonymous and is a speaker at its meetings. He has been involved in Alcoholics Anonymous for over fifteen years.

The Administrator further finds that on or about March 7, 1985, Respondent