Duncan, John, Harriet, and Eliza Jennett, House (Centerville MPS), 445 North 400 East, Centerville, 97001312
Ford-Rigby House (Centerville MPS), 1592 N. Main St., Centerville, 97001313
Harris-Tingey House (Centerville MPS), 269 E. Center St., Centerville, 97001314
Holland-Smith-Brown House (Centerville MPS), 19 South 200 East, Centerville, 97001315
Kilbourn-Leak House (Centerville MPS), 170 North 200 East, Centerville, 97001316
Porter, Nathan and Rebecca Cherry and Eliza Ford, Farmstead (Centerville MPS), 370 West 400 South, Centerville, 97001317
Rich-Steeper House (Centerville MPS), 415 S. Main St., Centerville, 97001318
Roberts, B.H., Louisa Smith and Cecilia Dibble, House (Centerville MPS), 315 South 300 East, Centerville, 97001319
Smith-Larsen House (Centerville MPS), 280 E. Center St., Centerville, 97001320
Streeper, William Henry and Mary, House (Centerville MPS), 1020 N. Main St., Centerville, 97001321
Taylor, John W., Janet (Nettie), and May Rich, House, 49 East 500 North, Farmington, 97001325
Thurston-Chase Cabin (Centerville MPS), 975 N. Main St., Centerville, 97001322
Walton, Franklin and Amelia, House (Centerville MPS), 98 West 280 South, Centerville, 97001323
Young Men's Hall—Tingey House (Centerville MPS), 85 South 300 East, Centerville, 97001324

WYOMING

Sweetwater County

Our Lady Sorrows Catholic Church, A at Broadway, Rock Springs, 97001326

[FR Doc. 97–27130 Filed 10–10–97; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Overseas Private Investment Corporation

Submission for OMB Review; Comment Request

AGENCY: Overseas Private Investment Corporation, IDCA.

ACTION: Request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), Agencies are required to publish a Notice in the **Federal Register** notifying the public that the Agency has prepared an information collection request for OMB review and approval and has requested public review and comment on the submission. OPIC published its first **Federal Register** notice on this information collection request on August 6, 1997, in 62 FR 42262, at which time a 60-calendar day comment period was announced. This comment period ended October 6, 1997. No comments were received in response to this notice.

This information collection submission has now been submitted to OMB for review. Comments are again being solicited on the need for the information, its practical utility, the accuracy of the Agency's burden estimate, and on ways to minimize the reporting burden, including automated collection techniques and uses of other forms of technology. The proposed form under review is summarized below.

DATES: Comments must be received on or before November 13, 1997.

ADDRESSES: Copies of the subject form and the request for review submitted to OMB may be obtained from the Agency Submitting Officer. Comments on the form should be submitted to the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

OPIC Agency Submitting Officer: Lena Paulsen, Manager, Information Center, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527; 202/336–8565.

OMB Reviewer: Victoria Wassmer, Officer of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, 202/395–5871.

Summary of Form Under Review

Type of Request: Revised form.
Title: OPIC's Expedited Screening Questionnaire—Downstream Investments.
Form Number: OPIC–168.
Frequency of Use: Once per project submission.
Type of Respondents: OPIC's Fund Managers.
Standard Industrial Classification Codes: All.
Description of Affected Public: OPIC's Fund Managers.
Reporting Hours: 1 hour per form.
Number of Responses: 150 per year.
Federal Cost: $918.00 annually.
Authority for Information Collection: Section 231(K) (1–2) of the Foreign Assistance Act of 1961, as amended.
Abstract (Needs and Uses): The questionnaire is completed by OPIC's Fund Managers. The Fund Managers will complete the information for companies in which the Fund proposes to invest. The information collected will be reviewed to determine the expected effects of the projects on the U.S. economy and employment, as well as on the environment, economic development, and worker rights abroad.

Dated: October 8, 1997.

James R. Offutt,

Assistant General Counsel, Department of Legal Affairs.

[FR Doc. 97–27132 Filed 10–10–97; 8:45 am]

BILLING CODE 3210–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By notice dated March 31, 1997, and published in the **Federal Register** on April 29, 1997, (62 FR 23268), Celgene Corporation, 7 Powder Horn Drive, Warren, New Jersey 07059, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacture of methylphenidate (1724) a basic class of controlled substance listed in Schedule II.

DEA has considered the factors in Title 21, United States Code, Section 823(a), as well as information provided by other bulk manufacturers, and determined that the registration of Celgene Corporation to manufacturer methylphenidate is consistent with the public interest at this time. 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: October 3, 1997.

John H. King,

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

[FR Doc. 97–27142 Filed 10–10–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 96–47]

City Drug Company: Revocation of Registration

On August 29, 1996, 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 revoke its DEA Certificate of Registration, AC5430450, and deny any pending

applications for registration under 21 U.S.C. 823(f), for reason that its continued registration would be inconsistent with the public interest pursuant to 21 U.S.C. 824(a)(4).

By letter dated September 19, 1996, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Mobile, Alabama on April 15, 1997, before Administrative Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, counsel for both parties submitted proposed findings of fact, conclusions of law and argument. On July 24, 1997, Judge Randall issued her Opinion and Recommended Ruling, recommending that Respondent's DEA Certificate of Registration be revoked and any pending applications for renewal of such registration be denied. In addition, Judge Randall recommended that favorable consideration be given to a new application for registration should Respondent present any persuasive evidence of proposed procedural changes for the dispensing of controlled substances. On August 4, 1997, Respondent filed a general objection to the Administrative Law Judge's decision, and on August 26, 1997, Judge Randall transmitted the record of these proceedings to the Acting Deputy Administrator.

By letter dated September 17, 1997, Judge Randall forwarded a letter from Respondent's counsel dated September 9, 1997, that set forth information concerning procedural changes implemented at Respondent and continuing education received by Respondent's owner. This letter was received by the Administrative Law Judge after the record had closed and been transmitted to the Acting Deputy Administrator. The Acting Deputy Administrator has not considered Respondent's September 9, 1997 letter in rendering his decision in this matter since it was submitted after the record had closed, and Respondent did not offer any explanation as to why this information was not submitted prior to the closing of the record.

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, with one noted exception, the Opinion 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 Respondent is one of five pharmacies located in Opp, Alabama and has been in existence for approximately 25 years. Joseph Grimes is the owner and pharmacist in charge of Respondent.

On March 2, 1992, a search warrant was executed at Respondent pharmacy as a result of an undercover operation conducted by a local police department. During the search, DEA investigators conducted a physical count of controlled substances on the premises using Respondent's pill counting machine, and collected all relevant controlled substance records for the period January 15, 1990 to March 2, 1992, except purchase invoices and records of controlled substances, if any, returned to suppliers. A DEA investigator later contacted Respondent's suppliers and obtained records of controlled substance sales to Respondent for the period January 15, 1990 to March 2, 1992.

Alabama law requires a pharmacy to conduct an inventory of controlled substances on the 15th day of January of each year. Included in the records seized during execution of the search warrant were these inventories conducted by Respondent for 1990, 1991, and 1992. Mr. Grimes testified at the hearing in this matter that when performing an inventory, he counts all individual dosage units of Schedule II controlled substances, and as permitted by Federal and state law, he estimates the quantities of Schedule III through V controlled substances.

Using Respondent's records, records from Respondent's suppliers, and the closing inventory conducted on March 2, 1992, DEA conducted several accountability audits. One audit of Schedule III and IV controlled substances was conducted using Respondent's January 15, 1990 inventory as the initial inventory figure and DEA's March 2, 1992 count as the closing inventory. This accountability audit revealed that Respondent could not account for 80,223 dosage units, including 18,774 dosage units of Darvocet/propoxyphene 100 mg. and 10,428 dosage units of Darvocet/propoxyphene 65 mg. In addition, the audit revealed an overage of 402 dosage units of hydrocodone 5 mg. (brand and generic).

An audit of the Schedule II controlled substance oxycodone 5 mg. for the period January 15, 1990 to January 15, 1992, revealed an overage of 859 dosage units. This unit used Respondent's January 15, 1990 inventory as the initial inventory figure, and its January 15, 1992 inventory as the closing inventory figure.

Another audit was conducted of Schedule III and IV controlled substances using Respondent's January 15, 1990 inventory as the initial inventory figure and its January 15, 1992 inventory as the closing inventory figure. This audit revealed shortages totaling 13,706 dosage units and overages totaling 705 dosage units.

Following execution of the search warrant, DEA organized prescription records taken from Respondent according to the prescribing doctor. Eleven of these doctors were provided copies of prescriptions attributed to them and each doctor reviewed his patient records in the presence of a DEA investigation to determine whether or not he had authorized the prescriptions found at Respondent pharmacy.

Prescriptions taken from Respondent pharmacy indicated that Dr. Rex Butler had prescribed a total of 2,427 dosage units of controlled substances to five patients. By affidavit dated March 19, 1997, Dr. Butler indicated that he had not authorized any of these prescriptions. Respondent provided affidavits from two of these patients and one of their relatives which indicated that they had witnessed Mr. Grimes receiving authorization from Dr. Butler for controlled substance prescriptions for them. Another of the patients indicated by affidavit that Dr. Butler had prescribed Limbitrol DS for him on several occasions. However, like Judge Randall, the Acting Deputy Administrator finds these patient affidavits to be of limited value since they do not specifically address the prescriptions at issue nor do they reference any time period for their statements. In addition, the Acting Deputy Administrator finds Dr. Butler's affidavit to be more reliable than the patients' affidavits, since Dr. Butler's affidavit is based upon a review of his patient records which were prepared and maintained during the relevant time period, whereas the patients' affidavits are based upon their recollection more than six years after the event.

Dr. Steven Davis declared in an affidavit dated March 3, 1997, that after reviewing the prescriptions taken from Respondent's files that were attributed to him and comparing them to his patient records, he determined that he had not authorized prescriptions for 20 specifically named patients, amounting to a total of approximately 2,650 dosage units of controlled substances. Respondent provided affidavits from patients or immediate family members of patients concerning Dr. Davis's

prescribing practices. The majority of these affidavits fail to address the specifically questioned prescriptions or to provide relevant time periods for their statements, and are therefore of limited value. However, two of the patients do indicate in their affidavits that they were prescribed the medication on the specific date at issue. Nonetheless, the Acting Deputy Administrator finds Dr. Davis' affidavit to be more reliable than the affidavits of these two patients since Dr. Davis' affidavit is based upon a review of his patient records which were prepared and maintained during the relevant time period, whereas the patients' affidavits are based upon their recollection more then six years after the event. As Judge Randall noted, the affidavit of the wife of one of the patients verified that her husband was prescribed Vicodin in December 1991 by Dr. Davis. Since Dr. Davis does not address in his affidavit whether or not he authorized this prescription, the Acting Deputy Administrator agrees with Judge Randall that the wife's affidavit ''warrant[s] a belief that this December 1991 prescription was authorized by Dr. Davis.''

Prescriptions taken from Respondent pharmacy indicated that Dr. James Guest had prescribed a total of 1,205 dosage units of Halcion and Xanax for one patient between June 25, 1990 and February 29, 1992. By affidavit dated February 13, 1997, Dr. Guest stated that he had last seen this patient on May 17, 1989, and had not authorized any of the prescriptions taken from Respondent pharmacy that were attributed to him. Respondent provided affidavit from the patient and her daughter which indicated that Mr. Grimes had telephoned Dr. Guest's office for authorization to dispense Halcion and Xanax. However, like many of the previously discussed affidavits, these affidavits fail to address the specific prescriptions in question or to provide any specific time period for their statements.

Respondent's prescription records indicated that Dr. Joe Sanders authorized the dispensing of 2,600 dosage units of propoxyphene N–100 or Darvocet N–100 to one patient between August 31, 1990 and February 1, 1992. But, in a letter dated June 4, 1993, Dr. Sanders wrote that he had last seen the patient on May 17, 1990, and had no record or recollection of calling in any prescriptions for the patient since that time.

According to Respondent's records, between January 19, 1990 and November 21, 1991, Respondent dispensed 2,280 dosage units of lorazepam 2 mg. to one patient as allegedly authorized by Dr. Kirit Joshi. However, by affidavit dated February 18, 1997, Dr. Joshi declared that while he has issued that patient prescriptions for other controlled substances, he had not authorized the lorazepam prescriptions for the patient. In an affidavit, the patient's husband stated that, ''[t]o my knowledge Joe Grimes has phoned Dr. Kiruit [sic] Joshi's office for lorazepam and other medication in 1990 and 1992 for my wife * * *.'' The Acting Deputy Administrator finds Dr. Joshi's affidavit to be more reliable than the husband's affidavit, since Dr. Joshi's affidavit is based upon a review of his patient record which was prepared and maintained during the relevant time period, whereas the husband's affidavit is based upon his recollection more than six years after the event.

Respondent's records indicate that Dr. D.A. Marsh telephoned two prescriptions to Respondent for an individual, one on November 25, 1991, for 18 dosage units of Fiorinal #3 with codeine, and the other on December 5, 1991, for 6 dosage units of Fiorinal #3 with codeine. In an affidavit dated February 19, 1997, Dr. Marsh declared that he did in fact see this patient on November 19 and 25, 1991, and that he did write her a prescription for 20 Fiorinal #3 with codeine on November 25, 1991. However, Dr. Marsh stated he did not orally authorize any prescriptions for this individual, and specifically denied authorizing the two prescriptions noted above. In an affidavit dated April 9, 1997, the patient stated that, ''[p]rescriptions for Fiorinal #3 were authorized for me by D.A. Marsh MD in November and December of 1991 and were filled at [Respondent] * * *. Some of these prescriptions were phoned in.'' She indicated that she was allergic to a drug prescribed for her by Dr. Marsh and that once he was informed of this allergy, ''Dr. Marsh authorized a prescription for 6 Fiorinal with codeine capsules for me.'' While the patient's affidavit might help explain the prescription in Respondent's files for the six Fiorinal #3 with codeine, it does not address the 18 dosage units allegedly dispensed pursuant to an oral prescription, on the same day Dr. Marsh admitted issuing the patient a written prescription for 20 dosage units. However, as with the other affidavits, the Acting Deputy Administrator finds Dr. Marsh's affidavit to be more reliable than that of the patient since it is based upon a review of his patient record which was prepared and maintained during the relevant time period, whereas the patient's affidavit is based upon her recollection more than six years after the event.

According to Respondent's records, between January 1, 1990 and March 2, 1992, Dr. Donald Newman orally authorized prescriptions for 2,600 dosage units of chlordiazepoxide 10 mg. for a specific patient. By affidavit dated February 18, 1997, Dr. Newman stated that while he did prescribe controlled substances on occasion to this patient, it was always in writing and he did not authorize any of the oral prescriptions for chlordiazepoxide found in Respondent's files. Respondent provided an affidavit from this patient dated April 9, 1997, who stated that, ''I have witnessed Joe Grimes calling Dr. Donald Newman's office for permission to refill Librium (chlordiazepoxide HCL) on several occasions during the period of January 1990 to January 1991.'' However, this affidavit does not address the specific prescriptions at issue. Again, the Acting Deputy Administrator finds Dr. Newman's affidavit to be more reliable than that of the patient since it based upon a review of his patient record which was prepared and maintained during the relevant time period, whereas the patient's affidavit is based upon her recollection more than six years after the event.

According to Respondent's records, Dr. Steven Price authorized five prescriptions for a total of 150 dosage units of controlled substances to three patients. As to the first patient, Dr. Price stated in an affidavit dated February 20, 1997, that while he had prescribed the patient Xanax in January 1991, he did not authorize the prescription for Xanax found in Respondent's files dated February 22, 1991. Regarding the second patient, Dr. Price denied prescribing diazepam 5 mg. for the individual on the dates listed on the three prescriptions found in Respondent's files. Finally, Dr. Price stated that he has no record of the patient whose name appeared on the fifth prescription attributed to Dr. Price. The first patient, in an affidavit dated April 9, 1997, stated that Dr. Price had prescribed Xanax for her in January and February 1991. This affidavit confirms Dr. Price's conclusion, after reviewing his patient's chart, that he had prescribed Xanax in January of 1991, yet conflicts with his conclusion concerning the February 1991 prescription. Regarding the second patient, Respondent provided an affidavit dated April 9, 1997, from an individual who stated that she could ''verify that [the patient] was prescribed Valium (diazepam) by Dr. Steven Price and sometimes the prescription was phoned into [Respondent]. I personally

picked up this medication on many occasions for [the patient].'' The affidavit fails to give a time period for her statements. The Acting Deputy Administrator finds Dr. Price's affidavit to be more reliable than those submitted by Respondent, since it is based upon a review of his patient records which were prepared and maintained during the relevant time period, whereas the patients' affidavits are based upon the recollection of individuals more than six years after the event.

During execution of the search warrant, investigators obtained from Respondent five prescriptions allegedly authorized by Dr. B.A. Santa Rossa for an individual for a total of 180 dosage units of proproxyphene 65 mg. and 120 dosage units of Wygesic. In his affidavit dated March 17, 1997, Dr. Santa Rossa stated that while he had prescribed controlled substances for this individual in the past, he always issued a written prescription for the drugs. In addition, a review of his patient record revealed that he had not authorized any of the five prescriptions attributed to him that were found in Respondent's files. Further, in his affidavit, Dr. Santa Rossa denied issuing a prescription to a second individual on June 8, 1991, for 30 dosage units of diazepam 10 mg. However, Respondent provided an affidavit from this second patient who stated that, ''according to my best judgment and recol[l]ection do attest to the fact that Joe Grimes has called for permission to fill diazepam 10 mg. in June 1991.'' As Judge Randall noted, ''[e]ven if this affidavit is given more credibility than Dr. Santa Rossa's affidavit, a total of 300 dosage units of controlled substances were dispensed, without authority, by the Respondent's pharmacists * * *.''

According to Respondent's records, Dr. Richard Spurlin authorized multiple prescriptions to six individuals which accounted for the dispensation of over 12,000 dosage units of controlled substances by Respondent. By affidavit, Dr. Spurlin stated that after reviewing his records for these patients, he determined that while he had at various times issued these individuals controlled substances prescriptions, he had not authorized any of the prescriptions found in Respondent's files. Respondent provided affidavits from four of these patients. Three of them indicated that they had observed Mr. Grimes telephoning Dr. Spurlin's office for authorization to fill or refill prescriptions. Yet, none of these affidavits address the specific prescriptions at issue nor do they provide a time period for the statements made. The other patient's affidavit indicated that ''Dr. Spurlin has authorized prescriptions for Xanax .25 mg. (alprazolam) and Halcion for me from 1988 to 1997.'' The Acting Deputy Administrator finds that while this patient references a general time period, like the other patients, she fails to address the specific prescriptions at issue. Therefore,the Acting Deputy administrator finds Dr. Spurlin's affidavit to be more reliable than those submitted by Respondent, since it is based upon a review of his patient records which were prepared and maintained during the relevant time period, whereas the patients' affidavits are based upon their recollection more than six years after the event.

In December 1992, DEA investigators asked Dr. Reddoch Williams to review prescriptions found in Respondent's files that indicated that they were authorized by him. By letter dated February 26, 1997, Dr. Williams certified that he had reviewed the original prescriptions and his patient filed. Dr. Williams also wrote that he had not authorized ''[Respondent] or any other person or pharmacy to fill or refill the prescriptions which are marked as 'forgery' or otherwise marked as not authorized by me.'' Some of Dr. Williams handwritten comments are difficult to read and other comments are not definitive in nature, being qualified with statements such as ''I believe'' or ''I think''. Therefore, the Acting Deputy Administrator declines to find that any of these prescriptions were unauthorized. However, in those instances where the prescriptions are clearly marked as forgeries without any qualifying language, the Acting Deputy Administrator finds that these prescriptions were not authorized by Dr. Williams. These unauthorized prescriptions accounted for the dispensation of over 1,100 dosage units of controlled substances. Three of the patients, whose names appeared on the prescriptions which were clearly marked as forgeries by Dr. Williams, provided affidavits. However, these affidavits did not provide any time period for their statements and the other only provided a general reference to a time period, but did not specifically reference the date of the prescription at issue. Like with the previously discussed affidavits, the Acting Deputy Administrator finds Dr. Williams' comments to be more reliable than the patients' affidavits, since his comments are based upon a review of his patient records which were prepared and maintained during the relevant time period, whereas the patients' affidavits are based upon their recollection more than six years after the event.

In conducting the accountability audits which revealed significant shortages, DEA investigators included the unauthorized prescriptions as drugs for which Respondent could account. Mr. Grimes testified at the hearing before Judge Randall that he never filled a prescription without a doctor's authorization, and that while he disputes the results of the accountability audits, he does not have any explanation for the shortages and overages revealed by the audits.

The state of Alabama has not withdrawn its licensing commission from Respondent. In addition, while arrested and charged, Mr. Grimes was ultimately found not guilty by a jury of all charges stemming from the undercover operation conducted by the local police department which led to the execution of the search warrant. Further, it is undisputed that there have never been any complaints about Respondent or Mr. Grimes made by any drug supplier, and no doctor or pharmacist has ever contacted Mr. Grimes about illegal prescriptions. Finally, Respondent introduced into evidence a letter from the co-chairman of a drug company attesting to Mr. Grimes' honesty and integrity.

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 or 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 F.R. 16,422 (1989).

Respondent contends that the Government has not met its burden of proof in establishing that Respondent's continued registration would be inconsistent with the public interest. Judge Randall concluded and the Acting Deputy Administrator concurs that all five factors are relevant in determining the public interest in this matter.

As to factor one, it is undisputed that the State of Alabama has not taken any action against Respondent pharmacy or its owner Mr. Grimes. Regarding Respondent's conviction record relating to controlled substances, it is also undisputed that neither Respondent pharmacy nor its owner Mr. Grimes has been convicted of any such offense.

Factors two and four, Respondent's experience in dispensing controlled substances and its compliance with state, Federal, or local laws relating to controlled substances, are clearly relevant in determining whether Respondent's continued registration would be inconsistent with the public interest. The Acting Deputy Administrator finds that Respondent pharmacy dispensed over 25,000 dosage units of controlled substances without authorization from a physician in violation of 21 U.S.C. 829. Respondent argues that the physicians whose names appeared on the prescriptions at issue could have forgotten to note in the patient chart that the telephone prescriptions had been authorized. Respondent further argues that a patient's recollection is more reliable, since a patient is more likely to remember what was actually prescribed to him or her. Respondent also contends that in instances where there was no patient affidavit, Mr. Grimes was able to recall the circumstances of the dispensing at issue.

The Acting Deputy Administrator concludes that it is highly unlikely that eleven different physicians forgot to note numerous prescriptions in patient charts which accounted for the dispensing of over 25,000 dosage units of controlled substances. Also as stated previously, most of the patients' affidavits are of little value since they do not address the specific prescriptions at issue nor do they provide a time period for the statements contained in the affidavits. In addition, the physicians' affidavits were based upon a review of patient records prepared contemporaneously with the events at issue, whereas the patients' affidavits and Mr. Grimes' testimony are based upon their recollection of events which occurred over six years ago.

Therefore, the Acting Deputy Administrator finds that Respondent pharmacy dispensed controlled substances in violation of 21 U.S.C. 829. In addition, Mr. Grimes violated his corresponding responsibility as set forth in 21 C.F.R. 1306.04, to ensure that controlled substances are only prescribed and dispensed for a legitimate medical purpose.

Additionally, pursuant to 21 U.S.C. 827, a registrant must maintain complete and accurate records of controlled substances received, sold, delivered or otherwise disposed of by him. The Acting Deputy Administrator finds that accountability audits of Respondent's controlled substances handling revealed that for the period January 15, 1990 to March 1992, Respondent could not account for over 80,000 dosage units of Schedule III and IV controlled substances. In addition, the audits revealed overages of some audited substances, including an overage of 859 dosage units of oxycodone 5 mg., a Schedule II controlled substance. In conducting these audits, the investigators included the unauthorized prescriptions in their calculation of the total amount of controlled substances dispensed by Respondent. Had Respondent not been given credit for these unauthorized dispensations, the shortages would have been significantly greater.

In its post-hearing filing, Respondent proposes a number of possible explanations for the audit discrepancies. First, Respondent argues that as allowed, it estimated the amount of Schedule III through V controlled substances on hand when conducting its yearly inventory, and consequently, it is possible that the overages and shortages could have resulted from these estimations. Respondent also argues that the audit results were possibly the result of a review by DEA of incorrect or incomplete receiving and/or return records. Next Respondent argues that it is possible that the audit discrepancies were the result of other prescription records not being examined at the time of the audit. In support of this argument, Respondent contends that in conducting the audit, DEA did not examine additional ledgers used by Respondent during the audit period. Finally, Respondent argues that another possible explanation for the audit results is that DEA's closing inventory conducted on March 2, 1992, was inaccurate since DEA used Respondent's pill counting machine without first verifying the accuracy of the machine.

The Acting Deputy Administrator concurs with Judge Randall's conclusion that these possibilities advanced by Respondent ''are mere speculation, unsupported by the record in this case.'' Respondent did not provide any specific evidence that would account for the over 80,000 dosage unit shortage of controlled substances. While it is permissible to estimate Schedule III through V controlled substances when conducting an inventory, clearly such estimations would not account for over 80,000 dosage units. In addition, a registrant cannot estimate Schedule II controlled substances, however, the audit revealed a significant overage of the one Schedule II controlled substance audited. The investigators who conducted the audits were confident that they had obtained all of the necessary records. It is significant to note that if one were to accept Respondent's argument that the receiving records were incomplete, then the shortages revealed by the audit should actually have been greater, since Respondent would have had to account for more controlled substances. As to the prescription ledgers that Respondent argues would have effected the audit, the investigator testified that those ledgers were examined, however, since they did not contain any information necessary for conducting an audit, they were discounted. Finally, Respondent did not present any evidence that its pill counting machine was not operating properly.

Thus, the Acting Deputy Administrator concludes that the preponderance of the evidence supports a finding that Respondent did not maintain complete and accurate records of controlled substances as required by 21 U.S.C. 827, as evidenced by the results of the audits. The Acting Deputy Administrator finds it extremely significant that had DEA not included the unauthorized prescriptions in the audit and given Respondent credit for those dispensations, the shortages would have been far greater.

As to factor five, the Acting Deputy Administrator concurs with Judge Randall's finding that Mr. Grime's failure to accept responsibility for the significant unexplained shortages and unauthorized dispensations of controlled substances indicates a potential threat to the public health and safety. Previously, DEA's then-Administrator found that a pharmacist's ''refusal to acknowledge the impropriety of his dispensing practices * * * give[s] rise to the inference that [he] is not likely to act more responsibly in the future.'' Medic-Aid Pharmacy, 55 FR 30,043 (1990); see also, Rocco's Pharmacy, 62 FR 3056 (1997).

The Administrative Law Judge concludes that ''[t]he Government has proven by a preponderance of the evidence that the Respondent's past

conduct would justify revocation of its DEA Certificate of Registration.'' Judge Randall further concluded that Respondent did not present any mitigating or rehabilitating evidence as it relates to its dispensing practices. Therefore, Judge Randall recommended that Respondent's DEA Certificate of Registration be revoked. Judge Randall further recommended however, that ''[s]ubsequently, should the Respondent provide any evidence of proposed procedural changes for the dispensing of controlled substances in a new application for a Certificate of Registration, and should such evidence be persuasive, then I would concur with a favorable decision concerning that subsequent application.''

The Acting Deputy Administrator agrees with the Administrative Law Judge that the Government has met its burden of proof and that Respondent's registration should be revoked. However, the Acting Deputy Administrator does not adopt Judge Randall's recommendation that favorable consideration will be given to a new application for registration should Respondent present persuasive evidence of procedural changes regarding the dispensing of controlled substances. A change in procedures, in and of itself, might not justify granting Respondent a new registration, since Mr. 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. Respondent is certainly free to apply for a new DEA Certificate of Registration. Any such application will be evaluated in light of all of the relevant circumstances in existence at that time to determine whether to grant the application.

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 AC5430450, issued to City Drug Company, be, and it hereby is, revoked. The Acting Deputy Administrator further order that any pending applications for renewal of such registration, be, and they hereby are, denied. This order is effective November 13, 1997.

Dated: October 7, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–27144 Filed 10–10–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By notice dated February 28, 1997, and published in the **Federal Register** on March 28, 1997, (62 FR 14944), Johnson & Johnson Pharmaceutical Partners, HC02 State Road 933, KMO.1 Makey Ward, HC–02 Box 19250, Gurabo, Puerto Rico 00778–9629, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Sufentanil (9740), a basic class of controlled substance listed in Schedule II.

DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Johnson & Johnson Pharmaceutical to manufacturer sufentanil is consistent with the public interest at this time. 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 class of controlled substance listed above is granted.

Dated: October 1, 1997.

John H. King,

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

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DEPARTMENT OF LABOR

Office of the Secretary

Privacy Act of 1974; Publication of a New System of Records; Amendments To Existing Systems of Records

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of a new system of records; amendments to existing systems of records.

SUMMARY: The Privacy Act of 1974 requires that each agency publish notice of all of the systems of records that it maintains. This document adds a new system of records to this Department's current systems of records. With the addition of this new system of records, the Department will be maintaining 145 systems of records. This document also proposes to revise the Routine Uses Category for two of the Department's existing systems of records. The proposed routine uses provide additional protection to the privacy interests of the participants in the surveys which are being conducted by the managers of the relevant systems of records. Finally, various administrative (non-substantive) changes are being made to three of the existing systems of records. Two of the three systems being amended administratively, are the same systems which are the subject of the proposed revised Routine Uses Category.

DATES: Persons wishing to comment on this new system of records and on the proposed new Routine Uses may do so by November 24, 1997.

EFFECTIVE DATE: Unless there is a further notice in the **Federal Register**, the new system of records, and the proposed amendments to the two existing systems, DOL/BLS–13, and DOL/BLS–17, will become effective on December 8, 1997. The remaining amendments, which relate to DOL/OAW–1, DOL/BLS–13 and DOL/BLS–17, are administrative (non-substantive), and therefore, will become effective on October 14, 1997.

ADDRESSES: Written comments may be mailed or delivered to Robert A. Shapiro, Associate Solicitor, Division of Legislation and Legal Counsel, 200 Constitution Avenue, NW., Room N–2428, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Miriam McD. Miller, Counsel for Administrative Law, Office of the Solicitor, Department of Labor, 200 Constitution Avenue, NW, Room N–2428, Washington, DC 20210, telephone (202) 219–8188.