

Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AC2513972, previously issued to Wendell Leondrus Chestnut, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for the renewal of such registration, be, and they hereby are, denied. This order is effective March 5, 1999.

Dated: January 5, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99-2467 Filed 2-2-99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 96-38]

Daniel Family Pharmacy; Continuation of Registration With Restrictions

On June 24, 1996, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Daniel Family Pharmacy (Respondent) of Galesburg, Illinois, notifying the pharmacy of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, AD2002626, pursuant to 21 U.S.C. 824(a)(2) and (a)(4), and deny any pending applications for registration pursuant to 21 U.S.C. 823(f).

By letter dated July 23, 1996, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Chicago, Illinois on March 11 through 14, 1997, before Administrative Law Judge Mary Ellen Bittner. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, counsel for both sides submitted proposed findings of fact, conclusions of law and argument. On July 7, 1998, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's DEA Certificate of Registration be continued subject to certain conditions. On July 27, 1998, the Government filed Exceptions to Judge Bittner's Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision. Thereafter, Judge Bittner transmitted the record of these proceedings to the then-Acting Deputy Administrator on August 11, 1998.

On September 30, 1998, Judge Bittner transmitted to the then-Acting Deputy

Administrator Respondent's Motion for Leave to File its Response to Government's Objection which was filed on September 29, 1998. In its motion, Respondent's counsel represented that the Government did not object to Respondent's request for additional time to file its response to the Government's exceptions and that no party would be prejudiced by allowing Respondent the opportunity to respond. By letter dated October 2, 1998,

Government counsel indicated that it did in fact object to Respondent being given additional time to respond to the Government's exceptions. Government counsel stated that the Government attorney who agreed to Respondent's request was not an attorney of record in these proceedings and was not authorized to agree to Respondent's request. Government counsel noted that 21 CFR 1316.66 provides the parties with the opportunity to file exceptions to the Administrative Law Judge's recommended decision within 20 days of the date of the decision and that the Administrative Law Judge can grant additional time past the 20 days for the filing of a response to any exceptions. Government counsel argued that Respondent did not file any response or request for additional time to file a response within 20 days of Judge Bittner's decision. In addition, the Government argued that no good cause was given by Respondent to file a response at such a late date; that its request is tantamount to a motion to reopen the record; and that allowing Respondent to respond to the Government's exceptions at such a late date would delay the publication of a final order in this matter.

Respondent replied to the Government's letter on October 5, 1998, and forwarded its Response to the Government's Exceptions to the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge. Respondent pointed out that it could not have filed anything regarding the Government's exceptions within 20 days of Judge Bittner's recommendation since the Government did not file its exceptions until the twentieth day, and that the delay in filing its response was due to the unavailability of Respondent's owner and the work schedules of Respondent's counsel. Respondent then noted that 21 CFR 1316.66 allows for extensions "for the filing of a response to the exceptions filed by another party if . . . no party will be prejudiced and . . . the ends of justice will be served thereby." Respondent argued given the delay that had already occurred in this proceeding,

"it is difficult to imagine how the government will be prejudiced if Daniel Pharmacy is allowed to file its Response 41 days after the filing for the Government's Exceptions."

The Deputy Administrator recognizes that the regulations permit the granting of additional time to file a response to exceptions, however Respondent has not given any reason why it did not even request an opportunity to file a response until two months after the Government's exceptions were filed. Nevertheless, the Deputy Administrator concludes that no party will be prejudiced by consideration of Respondent's response given the length of time that it has taken to complete these proceedings.

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

The Deputy Administrator finds that Respondent is a pharmacy that has been in existence since 1988 and is owned by a corporation, Daniel Pharmacy, Inc. with George Daniel and his wife holding 51 and 49 percent of the shares respectively, George Daniel is also the managing pharmacist of Respondent.

In January 1993, an individual who was cooperating with law enforcement after being arrested on a burglary charge went to Respondent on two occasions and obtained Vicodin, a Schedule III controlled substance, from Mr. Daniel without a prescription. On January 5, 1993, the cooperating individual was monitored by law enforcement personnel. He indicated to Mr. Daniel that he was getting ready to move out of state and said, "Hey, I thought you might give me some Vicodin or something just for the road * * *." Mr. Daniel gave the cooperating individual some Vicodin. During this meeting, the cooperating individual gave Mr. Daniel \$1,100.00 apparently to repay a personal loan. There is no evidence that the cooperating individual paid Mr. Daniel for the Vicodin.

The cooperating individual returned to Respondent on January 6, 1993. Again he was monitored by law enforcement

personnel. He indicated to Mr. Daniel that he was leaving town that day and stated that "I kind of thought you might give me a few more of that." Mr. Daniel gave the cooperating individual some Vicodin. On this occasion, the cooperating individual paid off his ex-wife's bill at the pharmacy, but did not pay for the Vicodin.

The cooperating individual was interviewed by law enforcement personnel on January 6, 1993, following his visit to Respondent. The individual stated that he had known Mr. Daniel since about 1987 and worked for Respondent delivering prescriptions. In 1989, he injured his back in an accident and was prescribed Vicodin. After his physician stopped prescribing him Vicodin in 1991, Mr. Daniel gave him Vicodin without a prescription. The cooperating individual stated that Mr. Daniel gave him Vicodin regularly and also provided him with morphine and Dilaudid, Schedule II controlled substances, and Tussionex, a Schedule III controlled substance, without prescriptions.

On January 7, 1993, a search warrant was executed at Respondent to obtain records. Mr. Daniel cooperated with law enforcement personnel during the search and consented to a search of his residence and another house next door to Respondent. During execution of the warrant, DEA investigators, assisted by one of Respondent's pharmacists, conducted a physical count of certain controlled substances for later use in an accountability audit. DEA conducted several audits of Respondent's handling of controlled substances. One audit was of selected Schedule II controlled substances for the period September 1, 1990 to January 7, 1993. The investigators used Respondent's written inventory dated September 1, 1990 for the initial inventory figure. This audit revealed that Respondent could not account for almost 2,500 dosage units of various strengths of Dilaudid and for 693 dosage units of Percodan. A separate audit was conducted for morphine sulfate covering the period August 13, 1992 to January 7, 1993 and revealed that Respondent could not account for 2.45 grams. In conducting this audit, the investigators used a zero beginning balance whereby Respondent was not held accountable for any morphine sulfate that it may have had on hand at the beginning of the audit period.

The investigators conducted a separate audit of various Schedule III and IV controlled substances. This audit covered the period February 6, 1992 to January 7, 1993, and used a zero beginning balance. The audit revealed

that Respondent could not account for 15,733 dosage units of Valium 10 mg. and 2,057 dosage units of Vicodin 5 mg. Again, by using a zero beginning balance Respondent was not held accountable for any of the substances that it may have had on hand at the beginning of the audit period. Therefore, these shortages would have been greater if in fact Respondent had any of the substances in stock on February 6, 1992. The audit revealed overages for the other audited Schedule III and IV substances which most likely was the result of using a zero beginning balance.

The Illinois Department of Professional Regulation (IDPR) conducted its own audit of Respondent's controlled substances using the records that DEA had obtained during the search warrant. The results of the IDPR audit were the same as those of DEA with respect to the controlled substances that both audited. The IDPR also audited Desoxyn, a Schedule II controlled substance, for the period September 1, 1990 to December 18, 1992. The audit revealed that Respondent could not account for approximately 4,750 dosage units.

On January 21, 1993, Mr. Daniel was indicted in the United States District Court for the Central District of Illinois and charged with two felony counts of distributing hydrocodone on January 5 and 6, 1993 in violation of 21 U.S.C. 841(a)(1). According to a DEA agent who was present during Mr. Daniel's proffer in the criminal matter on November 3, 1993, Mr. Daniel stated that he and the cooperating individual were friends; in 1990 the individual injured his back and as a result he was prescribed prescription painkillers; at some point the cooperating individual's physician stopped prescribing Vicodin to the individual, yet Mr. Daniel continued to deliver approximately 500 dosage units of Vicodin to the individual without prescriptions; and he also provided the individual with Tussionex, Dilaudid and morphine without prescriptions. The agent further testified that Mr. Daniel also indicated during his proffer that sometime before January 5, 1993, he realized that the individual had a drug problem after observing him take approximately 18 times the normal dosage of Tussionex. In addition, Mr. Daniel stated that on November 2 and 7, 1992, he obtained Dilaudid from other pharmacies in order to provide it to the individual without a prescription. According to the agent, Mr. Daniel stated that the individual signed over his trailer home to him in exchange for the Dilaudid. However, at the hearing in this matter, Mr. Daniel denied that he traded Dilaudid for the

individual's trailer home and that he ever indicated that this occurred during his proffer. Because of conflicting evidence regarding this issue, the Deputy Administrator does not find that Mr. Daniel gave the individual Dilaudid in exchange for the title to the individual's trailer home. Mr. Daniel further stated in his proffer that in December 1992, he gave the individual some morphine without a prescription because the individual had threatened to tell the authorities that Mr. Daniel had been giving him drugs without prescriptions. Finally during the proffer, investigators advised Mr. Daniel of the audit results. According to the agent, Mr. Daniel thought that he had given the individual approximately 500 Vicodin, and was surprised that the audit revealed a shortage of at least 2,000 dosage units.

Following his guilty plea, Mr. Daniel was convicted on October 18, 1994, regarding the unlawful distribution of Vicodin to the cooperating individual on January 5, 1993. He was sentenced to two years' probation and ordered to spend 60 days in a work release facility, to perform community service and to pay a fine.

On February 23, 1996, the IDPR and Respondent and Mr. Daniel entered into a consent order providing, among other things, that (1) Mr. Daniel's pharmacist license would be suspended for six months and then placed on probation for four years and six months; (2) during the suspension, Mr. Daniel would successfully complete 15 hours of a Board-approved pharmacy law course in addition to his continuing education requirements; (3) Mr. Daniel would pay a fine; (4) Respondent's pharmacy license would be placed on probation for 5 years; and (5) during the pharmacy's probation, Mr. Daniel would be required to maintain a perpetual inventory of Schedule II drugs, allow only authorized licensees access to the pharmacy and cause the pharmacy to submit to random IDPR inspections. It is undisputed that Respondent and Mr. Daniel have thus far complied with the terms of the consent order.

On January 17, 1997, IDPR conducted a controlled substance inspection and a pharmacy inspection at Respondent. The only violation discovered during the controlled substance inspection involved Respondent's failure to timely submit several duplicate prescription blanks to the appropriate state agency. Regarding the pharmacy inspection, Respondent failed to maintain an updated copy of a specific reference book and violated the requirements that the pharmacy technician initial hard copies of prescriptions and that

pharmacists date computer printouts. The IDPR investigator also noted that Mr. Daniel did not start the perpetual inventory of Schedule II controlled substances until January 1, 1997. Mr. Daniel testified at the hearing in this matter that no one explained exactly how a perpetual inventory should be taken, but that he is now properly maintaining a perpetual inventory after discussing the methodology with the IDPR investigator.

At the hearing in this matter, Mr. Daniel testified that he first gave the cooperating individual Vicodin without a prescription in 1991 believing that the individual's physician would authorize the dispensation. Mr. Daniel testified that "[I] made my big mistake of letting him have [Vicodin], thinking that I could call the doctor Monday morning and get it okayed." According to Mr. Daniel, he felt "very sick" after being told by the individual's physician not to give the individual any more Vicodin. Mr. Daniel further testified that the individual returned about a month later and persuaded Mr. Daniel to give him some Vicodin without a prescription. Mr. Daniel acknowledged that he gave the individual the Vicodin knowing that his physician would no longer prescribe it and that he was not threatened by the individual on this occasion. However, Mr. Daniel also testified that "[a]fter the first couple of times he started to threaten that he would go to the authorities . . .," and that "I became scared enough to the point where it seemed that my only way out was to give it to him. And I tried to resist for awhile each time, but each time he would coax me or talk me into doing it."

Mr. Daniel testified that after being told that Respondent did not have any Dilaudid, the individual threatened to "really cause big problems for you because you've got shortages more than you'd even believe." According to Mr. Daniel, the individual also threatened to "get physical," made threatening phone calls to Mr. Daniel's wife, and passed two threatening letters to him. However, Mr. Daniel testified that initially he did not believe the individual's threats and one of Respondent's pharmacists testified that he never observed Mr. Daniel acting nervous or upset when he was with the individual. Mr. Daniel testified that he gave the individual Vicodin seven or eight times, Tussionex and morphine once and Dilaudid two times, all without prescriptions.

According to one of Respondent's pharmacists who testified in this proceeding, sometime in December 1992 Mr. Daniel instructed all of Respondent's employees not to allow the cooperating individual in the

pharmacy and to call the police if necessary because the individual was blackmailing him. Yet, Mr. Daniel allowed the individual in the pharmacy on January 5 and 6, 1993, and gave him Vicodin without a prescription. Mr. Daniel stated that he did so because he believed that the individual was moving out of state and "[b]ecause I was so sick and tired of what he had put myself and my family through and what I had stupidly done to start the whole thing, I just wanted him out of my life forever." * * *

Regarding the shortages discovered during the accountability audits, Mr. Daniel testified that the controlled substances that he provided to the cooperating individual would not account for the discrepancies, noting that he did not give the individual some of the drugs that had shortages, such as Valium. Mr. Daniel testified that following his arrest, he received information that the cooperating individual as well as one of Respondent's pharmacy technicians were stealing controlled substances from Respondent. Respondent introduced into evidence an affidavit from a woman who indicated that between 1987 and 1993 the cooperating individual frequently contacted her then-husband and offered to sell him drugs, including Valium, Vicodin and Dilaudid that the individual admitted stealing from Respondent. According to the woman, some of the bottles the individual brought to her home "were the bottles that pharmacists keep behind their counters and from which they fill prescriptions." She further stated that according to the individual he usually stole drugs from Respondent on Thursdays when the pharmacy received its drug shipments. According to Mr. and Mrs. Daniel, controlled substance orders were usually delivered on Thursdays and Mr. Daniel usually took Thursdays off.

At the hearing, Mr. Daniel conceded that although the cooperating individual told him that there were shortages at Respondent, he did not conduct any audit to verify whether the individual's assertions were accurate. He also testified that had he performed an audit he would have known that Respondent could not account for 15,000 dosage units of Valium. However, Mr. Daniel also acknowledged that he conducted a biennial inventory of controlled substances on December 18, 1992, and it does not appear that he noticed that such a large quantity of Valium was missing. One of Respondent's pharmacists testified at the hearing that he considered the shortages revealed by the audit to be of serious concern.

According to Mr. Daniel and another of Respondent's pharmacists there are new security measures in place to prevent unauthorized access to controlled substances. After Mr. Daniel was arrested, the cabinet containing Schedule II controlled substances was sealed with a headlock and the key was put in an area where the registered pharmacist could get it, and that only staff personnel were allowed in the prescription filling area. Yet, Mr. Daniel conceded that all of the employees knew where the key to the Schedule II cabinet is kept, but that the pharmacy is so small that "it would be about impossible for someone to get into the cabinet without the pharmacist knowing." However, Mr. Daniel also conceded that Respondent is the same size as it was when controlled substances were allegedly stolen and no one saw either the pharmacy technician nor the cooperating individual taking any controlled substances.

According to Respondent's pharmacist who testified at the hearing, he conducted a physical inventory of Respondent's controlled substances on March 2, 1997 and found no discrepancies with respect to Schedule II controlled substances and only minor shortages with respect to Schedules III, IV and V controlled substances. The pharmacist indicated that these shortages could be the result of miscounting, outdated items in process for return, and/or broken tablets. He also testified that Respondent is now doing more frequent inventories and audits.

Both Mr. Daniel and Respondent's other pharmacist who testified at the hearing indicated that unlike chain pharmacies in the area, Respondent offers its customers drive-up window service, prescription compounding, nutritional co-therapy, free local and out-of-town delivery, monthly charge accounts and after hours service. Mr. Daniel testified that other independent pharmacies may offer similar services, however no other pharmacy within 50 miles offers prescription compounding which is a service that is especially needed by senior citizens.

A former director of the Illinois Pharmacists Association (IPA), and a member of the Illinois Board of Pharmacy (Board), who is also a former president of the IPA, testified that in evaluating this case they would defer to the action taken by the Board, which did not take any action against Respondent's Illinois controlled substances license. The former IPA director also testified that if Respondent's DEA registration is revoked, the pharmacy will close because controlled substances are such

a substantial part of a pharmacy's business. He further expressed his concern with the impact on small towns when independent pharmacies go out of business, but conceded that he would also be concerned if a pharmacy maintains sloppy records and has significant shortages and thefts.

Both Mr. Daniel and Respondent's other pharmacist testified Respondent would go out of business if it loses its DEA registration. Controlled substances account for approximately 30 percent of Respondent's business and in their opinion customers will not patronize a pharmacy unless they can have all of their prescriptions filled there. Mrs. Daniel testified that they have received offers to buy Respondent however the offers have been substantially less than what was paid for the pharmacy.

Mr. Daniel testified that if permitted to keep Respondent's DEA registration, he would be willing to conduct regular physical inventories of controlled substances, to submit records of such inventories and computer records to DEA or the IDPR, to have DEA perform random inspections, to pay for a third party to perform physical counts and submit records to DEA, and to hire a pharmacist other than himself to be Respondent's pharmacist in charge. Mr. Daniel further testified that he would never again engage in the same type of misconduct that he did with the cooperating individual, and that "I will never put myself and my family and my business and everybody in that kind of position, no."

Finally, Respondent introduced into evidence letters that were submitted on Mr. Daniel's behalf during the criminal proceedings to the United States District Court for the Central District of Illinois. These letters essentially state that Mr. Daniel was active and well-regarded in the community, concerned for his family, and responsible in practicing his profession.

Pursuant to 21 U.S.C. 824(a)(2), the Deputy Administrator may revoke a DEA Certificate of Registration upon a finding that the registrant "has been convicted of a felony * * * relating to any substance defined * * * as a controlled substance. * * *" In addition, 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 application for such registration, 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., 54 FR 16,422 (1989).

First, the Deputy Administrator must determine whether 21 U.S.C. 824(a)(2) is a basis for revocation in these proceedings. While the Order to Show Cause raised both 21 U.S.C. 824(a)(2) and (a)(4) as grounds for the proposed revocation, the issue as proposed in the Government's Prehearing Statement and framed in the Prehearing Ruling issued by Judge Bittner referred only to whether Respondent's continued registration would be inconsistent with the public interest pursuant to 21 U.S.C. 824(a)(4).

Throughout the prehearing proceedings, Respondent argued in various filings that there is no basis for the revocation of Respondent's DEA registration since the statute refers to acts and convictions of the registrant to support such action, and the registrant in this case is the pharmacy, not Mr. Daniel. Respondent argued that the acts and conviction of Mr. Daniel should not be imputed to Respondent. The Government argued that DEA has consistently held that the actions and/or conviction of a natural person who is an owner, officer or key employee, or has some responsibility for the operation of the registrant's controlled substances business are considered in determining whether a pharmacy's registration should be revoked. The Government cited, among others, *Maxicare Pharmacy*, 61 FR 27,368 (1996) and *Farmacia Ortiz*, 61 FR 726 (1996) for this proposition.

Subsequent to the issuance of the Prehearing Ruling, on February 25, 1997, Judge Bittner issued a Memorandum to Counsel finding that Mr. Daniel's conduct is relevant to the issue of whether Respondent's continued registration is inconsistent with the public interest.

Thereafter, on March 5, 1997, Respondent moved to strike the Order to Show Cause to the extent that it referred to 21 U.S.C. 824(a)(2) as a basis for revocation and again argued that the section refers to a registrant's felony conviction and since Mr. Daniel is not the registrant, this provision does not apply. In a Memorandum to Counsel and Rulings dated March 7, 1997, Judge Bittner noted that the parameters of a proceeding are established by the Prehearing Ruling and since the issue framed in the Prehearing Ruling referred only to 21 U.S.C. 824(a)(4) as a basis for revocation, 21 U.S.C. 824(a)(2) is not at issue in this proceeding.

However, the Deputy Administrator agrees with Judge Bittner that had the Government not waived reliance on 21 U.S.C. 824(a)(2) in its Prehearing Statement, Mr. Daniel's conviction would constitute grounds for revoking Respondent's registration pursuant to that section. DEA has consistently held that a corporate registrant's registration may be revoked based upon the controlled substance-related felony conviction of an officer, agent or employee. As Judge Bittner noted, the then-Administrator found in *Lynnfield Drug, Inc.*, 42 FR 8435 (1977), "[t]o hold otherwise would result in the revocation of the registration of a feloniously violative sole proprietor while denying the same sanction to an equally violative registrant, merely because the latter had adopted a corporate or partnership form. Such a result would not only be not equitable, but would be contrary to the legislative intent behind the enactment of sections 303 and 304 of the Controlled Substances Act."

Notwithstanding that 21 U.S.C. 824(a)(2) cannot be relied upon as a basis for revocation in this proceeding, the Deputy Administrator concurs with Judge Bittner that Mr. Daniel's conduct and his conviction may be considered under 21 U.S.C. 823(f) and 824(a)(4). DEA has consistently held since 1984, when 21 U.S.C. 824(a)(4) was added as a ground for revocation, that the conduct of owners, agents and/or key employees constitute a basis for revoking the registrations of corporate registrants upon a finding that the continued registration would be inconsistent with the public interest. See, *Dobson Drug Co., Inc.* 56 FR 46,445 (1991).

In evaluating the factors listed in 21 U.S.C. 823(f), the Deputy Administrator finds that while no action has been taken by the State of Illinois against Respondent's controlled substance license, the Board has required Respondent to maintain a perpetual inventory of its Schedule II controlled

substances. Therefore, Respondent's handling of controlled substances has been affected by the Board's action. But, Respondent is currently authorized to handle controlled substances in Illinois. As Judge Bittner noted, "[i]nasmuch as state authorization to handle controlled substances is a necessary but not sufficient condition for DEA registration * * * this factor is not dispositive."

As to factors two and four, it is undisputed that Mr. Daniel dispensed Vicodin and other controlled substances without a prescription in violation of 21 U.S.C. 841(a)(1). The Deputy Administrator finds that Mr. Daniel's explanation that he was being threatened by the cooperating individual does not justify or excuse his behavior. First, Mr. Daniel himself admitted that initially he did not take the cooperating individual's threats seriously. Second, the other pharmacist at Respondent testified that Mr. Daniel did not appear nervous or upset when he observed Mr. Daniel with the cooperating individual. Finally, if in fact Mr. Daniel felt threatened by the cooperating individual he should have reported it to the proper authorities rather than continuing to unlawfully dispense controlled substances to him for over a year.

In addition, the significant shortages revealed by the audits indicate that Respondent did not maintain complete and accurate records of its handling of controlled substances as required by 21 U.S.C. 827. While there is some evidence that controlled substances were being stolen from Respondent, this does not minimize Respondent's responsibility for the shortages. It is quite disturbing that Mr. Daniel did not detect that over 17,000 dosage units were missing from Respondent in less than a one year period. As a DEA registrant, Respondent must ensure that controlled substances are properly dispensed. Respondent clearly abrogated this responsibility.

The Deputy Administrator notes that according to Respondent's pharmacists, more frequent inventories are now being conducted at Respondent and access to the controlled substances has been limited.

Regarding factor three, it is undisputed that Mr. Daniel was convicted of a felony relating to controlled substances, and as discussed above, Mr. Daniel's conviction is properly considered in determining what action to take against Respondent's registration.

The Deputy Administrator agrees with Judge Bittner that there was no evidence presented of other conduct by Mr.

Daniel or Respondent that would threaten the public health and safety.

Judge Bittner concluded that the Government made a prima facie case for revoking Respondent's DEA Certificate of Registration. However, she recommended that Respondent should nonetheless be permitted to remain registered. While expressing extreme concern regarding Mr. Daniel's "egregious abuse of his responsibilities as a pharmacist and as a DEA registrant," Judge Bittner also found that "Mr. Daniel seemed genuinely remorseful and that * * * he now understands the enormity of his misconduct." Judge Bittner recommended that Respondent's continued registration be subject to the conditions that:

(1) Respondent maintain a perpetual inventory of all controlled substances for at least three years following issuance of a final order in this proceeding;

(2) Respondent verify the perpetual inventory by a physical count, reduced to writing, of all controlled substances for each calendar quarter of that three year period;

(3) Respondent submit the perpetual inventory and quarterly verification to the Special Agent in Charge of the DEA field office having jurisdiction over Respondent; and

(4) Respondent consent to undergo unannounced inspections by DEA diversion investigators, without an administrative inspection warrant.

The Government filed exceptions to Judge Bittner's recommended decision objecting to the continuation of Respondent's registration on the sole basis that George Daniel appears remorseful. The Government argued that Mr. Daniel was remorseful to the extent that he got caught and that his DEA registration is now threatened with revocation; that Mr. Daniel refused to take any responsibility for the shortages; and that Mr. Daniel's contention that he was threatened into unlawfully dispensing controlled substances is hard to believe. In its response to the Government's exceptions, Respondent argued that Judge Bittner's assessment of George Daniel's credibility should control and that there is substantial evidence in the record to support her finding that Mr. Daniel is remorseful. In addition, Respondent again indicated that it is agreeable to even stricter conditions being imposed on its registration than those recommended by Judge Bittner.

The Deputy Administrator is deeply concerned by the egregious conduct of Respondent and Mr. Daniel. Mr. Daniel actively diverted controlled substances

by dispensing them without a prescription and allowed additional significant diversion to occur as evidenced by the shortages revealed during the audits. However, the Deputy Administrator notes that this conduct occurred in January 1993. Had this case been adjudicated at that time, or even right after his criminal conviction in October 1994, the Deputy Administrator would have revoked Respondent's DEA Certificate of Registration. But, in the subsequent six years, Respondent has maintained its DEA registration and available evidence indicates that it has acted in a responsible manner as demonstrated by the January 1997 state inspection which revealed only minor violations. In addition, the Deputy Administrator concurs with Judge Bittner's conclusion that Mr. Daniel has exhibited remorse for his actions, and finds it significant that Respondent is the only pharmacy in the area that performs prescription compounding. Therefore, the Deputy Administrator concludes that it would not be in the public interest to revoke Respondent's registration at this time. This decision however, should in no way be interpreted as an endorsement of the past illegal behavior of Mr. Daniel and Respondent. Mr. Daniel's remorse and the fact that available evidence indicates that the pharmacy has acted responsibly in the past six years provide adequate assurance that the prior illegal activity at Respondent will not be repeated.

However, the Deputy Administrator agrees with Judge Bittner that some restrictions must be placed on Respondent's registration to adequately monitor Respondent's handling of controlled substances and to protect the public health and safety. Therefore, Respondent's registration shall be continued subject to the following restrictions for three years:

(1) Respondent shall maintain a perpetual inventory of all controlled substances.

(2) Respondent shall verify the perpetual inventory by a physical count, reduced to writing, of all controlled substances for each calendar quarter of the three year period.

(3) Respondent shall submit the perpetual inventory and quarterly verification to the Special Agent in Charge of the DEA Chicago Field Division or his designee.

(4) Respondent shall arrange for audits to be conducted two times per year by an independent auditor at Respondent's expense with the results submitted to the Special Agent in Charge of the DEA Chicago Field Division or his designee.

(5) Respondent shall consent to unannounced inspections by DEA personnel without requiring an administrative inspection warrant.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 C.F.R. 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AD2002626, previously issued to Daniel Family Pharmacy, be and it hereby is continued, subject to the above described restrictions. This order is effective March 5, 1999.

Dated: January 28, 1999.

Donnie R. Marshall,

Deputy Administrator.

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BILLING CODE 4410-09-M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Services—Washington, DC.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before March 22, 1999. Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records

covered by a proposed schedule. These, too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

ADDRESSES: To request a copy of any records schedule identified in this notice, write to the Life Cycle Management Division (NWML), National Archives and Records Administration (NARA), 8601 Adelphi Road, College Park, MD 20740-6001. Requests also may be transmitted by FAX to 301-713-6852 or by e-mail to records.mgt@arch2.nara.gov.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

FOR FURTHER INFORMATION CONTACT: Michael L. Miller, Director, Modern Records Programs (NWM), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740-6001. Telephone: (301)713-7110. E-mail: records.mgt@arch2.nara.gov.

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs the records to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational

unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

Schedules Pending

1. Department of the Air Force (N1-AFU-99-5, 5 items, 2 temporary items). Architectural and engineering drawings pertaining to Air Force facilities and structures in Panama that were not long-lasting or historically significant. Records relating to structures of historical or architectural significance are proposed for permanent retention.

2. Department of the Army, Army Reserve (N1-AU-98-3, 2 items, 2 temporary items). Records pertaining to the Individual Mobilization Augmentation Program under which selected individuals may be mobilized to support the President. Included are administrative reference files relating to such matters as exceptions to policy, budget and annual training and supervisors' files on individual designees.

3. Department of the Army (N1-AU-98-13, 46 items, 46 temporary items). Short-term, temporary records accumulated by U.S. Army South (USARSO). The records were previously approved for disposal and consist of such files as pharmacy stock inventory reports, household shipment bills of lading, prisoner personal property reports, and military police reports. Records are proposed for immediate disposal upon USARSO's relocation from Panama to Puerto Rico. Electronic copies of documents created using electronic mail and word processing are also proposed for disposal.

4. Department of Health and Human Services, National Institutes of Health (N1-443-98-3, 3 items, 2 temporary items). Files relating to procedures governing budget generation, including electronic copies created using electronic mail, word processing, spreadsheet applications and database management applications. Recordkeeping copies of budget