regulations as confirmed through a DEA on-site inspection of the premises. 74 FR at 2128 (citing 21 CFR 1310.71–1301.93). Factor six, in contrast, is a catchall category that is designed to give DEA wide latitude to consider all evidence that might reasonably bear on the suitability of an applicant for registration. In other words, even if a registrant has promised to undertake security procedures sufficient to obtain a favorable finding under factor five, if other evidence (not covered by factors one through five) casts doubt on whether the applicant can be entrusted with the responsibility of a DEA manufacturing registration, such evidence may be considered under factor six.

Consider, for example, if a person were seeking to become registered as a manufacturer of oxycodone, and the applicant promised to install and maintain in the facility all the physical security measures and employee screening procedures required by the regulations. Assume further that evidence came to light that the main investor in the facility, who planned to make the decisions as to how the facility would distribute oxycodone, admitted that he obtains oxycodone illegally and uses it for ''recreational'' purposes on a weekly basis. In such circumstances, it would certainly be appropriate for DEA to draw an adverse inference under factor six based on such person's illicit activity involving oxycodone—regardless of whether the applicant made assurances that it would comply with the security regulations. Thus, I cannot adopt Respondent's suggestion that Mr. Doblin's regular marijuana use should be ignored as a factor relevant to his application.

Nonetheless, it bears repeating that the ultimate decision in this matter did not turn on consideration of Mr. Doblin's marijuana activity. As stated in the Final Order, two other independent grounds existed for denying the application and, therefore, the same result would have been reached had I determined that Mr. Doblin's marijuana activity were irrelevant.

To be clear, if I determined that the proposed registration were consistent with United States obligations under the Single Convention and further that the supply of marijuana available to researchers in the United States were inadequate within the meaning of 21 U.S.C. 823(a)(1), it is conceivable that arrangements could have been made to mitigate the concerns regarding Mr. Doblin's marijuana activity. For example, under a conditional grant of registration or memorandum of agreement, sufficient terms perhaps could have been imposed to ensure that Mr. Doblin would not be allowed to have access to the growing facility and would have no role in any decision making relating to management of the facility or the distribution of marijuana. However, consideration of such an approach was not feasible here given the other grounds for denying the application.

IV. Conclusion

For the foregoing reasons, Respondent's motion for reconsideration is hereby denied. The administrative record is modified as indicated herein and in my December 2, 2010, order. The January 14, 2009, Final Order, as supplemented by this order, is effective on September 7, 2011.

Dated: August 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21064 Filed 8–17–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Joe C. Fermo, M.D.; Revocation of Registration

On September 30, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Joe C. Fermo, M.D. (Registrant), of Tulsa, Oklahoma. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration, BF7430781, as well as the denial of any pending applications to renew or modify his registration, on the ground that his ''continued registration would be inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order specifically alleged that on February 23, 1990, Registrant was convicted in the District Court for Oklahoma County, State of Oklahoma, of ten counts of submitting false claims to the Oklahoma Department of Human Services in violation of Oklahoma law, and that on June 20, 1990, the United States Department of Health and Human Services excluded him from participating in federal health care programs under 42 U.S.C. 1320a–7(a). *Id.* at 1–2. The Order further alleged that based on his convictions, on June 21, 1990, the Oklahoma State Board of Medical Licensure placed his medical license on probation and that Registrant materially falsified three separate applications (in 1991, 1994, and 1997) to renew his DEA registration by failing to disclose the state board's action. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).[1]

Finally, the Show Cause Order alleged that on August 27, September 24, and September 26, 2007, an undercover officer had obtained prescriptions from Registrant for alprazolam (at all three visits) and propoxyphene (at the first two visits), both of which are schedule IV controlled substances. *Id.* The Order further alleged that these prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice in violation of Federal and State laws. *Id.* (citing 21 CFR 1306.04 and Okla. Admin. Code 475.30–1–3(a)).

On or about October 5, 2009, the Show Cause Order, which also notified Registrant of his right to either request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing so, and the consequence if he failed to do so, was served on Registrant by certified mail addressed to him at the address of his registered location. *Id.* at 2–3 (citing 21 CFR 1301.43). Since service of the Show Cause Order, more than thirty days have now passed and neither Registrant, nor anyone purporting to represent him, has either requested a hearing or submitted a written statement in lieu of a hearing. *See* 21 CFR 1301.43(b)–(d). Accordingly, I find that Registrant has waived his rights to a hearing or to submit a written statement. *Id.* 1301.43(d). I therefore issue this Decision and Final Order without a hearing based on relevant evidence contained in the investigative record submitted by the Government.

Findings

Registrant is the holder of DEA Certificate of Registration, BF7430781, which authorizes him to dispense controlled substances in schedules II through V as a practitioner at the registered location of 5970 E. 31 St., Suite O, Tulsa, Oklahoma. While his registration was to expire on September 30, 2010, on August 13, 2010, Registrant filed a renewal application. In accordance with the Administrative Procedure Act and DEA regulations, I find that Registrant's registration remains in effect pending the issuance

[1] The Show Cause Order alleged that in March 2001, Registrant and DEA entered into a Memorandum of Agreement (MOA) which settled a Show Cause Proceeding filed in April 2000 based on the allegations described above. Show Cause Order at 2. The Show Cause Order also alleged that under the MOA, Registrant surrendered his registration and was allowed to reapply no earlier than March 2004, and that in October 2004, DEA issued him a new registration. *Id.*

of this Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i).

On August 27, 2007, an Agent with the Oklahoma Bureau of Narcotics went to Registrant's office to perform an undercover visit with Merli Fermo, M.D., Registrant's wife, who was also a DEA registrant.[2] Upon meeting the receptionist, to whom she paid $65, the Agent was told that she would have to wait one hour to see Merli Fermo and was asked if she wanted to see Registrant, who was available immediately. The Agent agreed and was taken to his office.

After the Agent and Registrant discussed the former's having spent some time in Minnesota and why she had returned to Oklahoma, who she lived with, how she was supporting herself, and her address, Registrant asked the Agent: ''So what do you want me to put you on?'' The Agent replied: ''I've been on Xanax. Two milligrams.'' Registrant then asked the Agent if she had ''been on it for a while?'' The Agent replied that she had been, that she had ''continued it when'' she had gone to Minnesota, and had gotten it ''from a doctor up there.''

Registrant then asked: ''You're taking Xanax three times a day?''; the Agent replied ''four times a day.'' Registrant responded: ''It says three times a day,'' to which the Agent said, ''I know but it was increased up there.'' Registrant then told the Agent to ''take it two times a day. Two milligrams.'' The Agent asked: ''So I'm only get[ing] it two times a day?'' Registrant replied affirmatively and asked, ''What else are you taking?'' The Agent answered: ''I was taking Darvocet too.''

Registrant then asked ''are you having some pain?'' The Agent replied: ''Oh, every once in a while.'' Registrant told the Agent to ''[t]ake it two times a day and I'll give you a hundred''; the Agent replied: ''Okay. I wish you'd give me the four on this Xanax though.'' After several comments which were unintelligible, Registrant and the Agent discussed how far the latter had lived from Minneapolis, whether the Agent went there much when she lived in Minnesota, and Registrant's having previously lived in the Minneapolis area. Before the visit ended, Registrant gave the Agent prescriptions for 100 Xanax (alprazolam) 2 mg and 100 Darvocet-N (propoxyphene) 100 mg, both of which are schedule IV controlled substances, *see* 21 CFR 1308.14(b), (c), as well as Celera, a non-controlled anti-depressant.

On September 24, 2007, the Agent returned to Registrant's office and paid the receptionist $65. While the Agent was scheduled to see Registrant's wife, when informed that the latter was not available, she agreed to see Registrant, and after a short wait, was taken to his office.

Registrant asked the Agent how she was doing; she replied ''great.'' Registrant then asked ''what's going on with you?'' The Agent answered: ''Not a thing. I wonder if I could get a hundred and twenty of the Xanax instead of a hundred?'' Registrant asked why she wanted one hundred twenty; the Agent answered: ''I ran out.'' [3] Registrant then said: ''No, not if you take it down * * * the way it is prescribed for you, you wouldn't run out.'' After the Agent said ''I know,'' Registrant stated—in contrast to his instruction at the previous visit to take the Xanax twice a day—''Just take it three times a day, that's precisely why it's controlled because people have a tendency to (*Inaudible*) take it more than what's prescribed.'' Registrant then apparently warned the Agent that she could have seizures if she took more than what he prescribed ''and then if you don't take it for some reason or another'' and added ''it's not good to be doing that.''

After telling the Agent that she could take the Xanax ''three times a day,'' Registrant asked her: ''Do you still need the Darvocet?''; the Agent answered: ''Yes.'' After a conversation about such subjects as how much social security the Agent was getting, what type of work she had previously done, her shopping habits, and whether she had a boyfriend, Registrant told the Agent to take the Celexa because it is an anti-depressant that works with Xanax and would help her to get going in the morning. After still more conversation about the Agent's social life, Registrant gave her new prescriptions for 100 Xanax 2 mg, 100 Darvocet-N 100 mg, and Celexa. Shortly thereafter, the visit ended.[4]

[2] Merli Fermo has since passed away.

[3] Based on the dosing instruction he gave the Agent at the initial visit, the Xanax should have lasted 50 days; the Agent was thus seeking the drug approximately three weeks early.

[4] The Government also submitted a copy of the Information filed by the State of Oklahoma charging Registrant with ten counts of submitting false claims to the Oklahoma Department of Human Services; a ''Deferred Sentence, Plea of Guilty, Summary of Facts'' filed in the state court proceedings; a June 20, 1990, letter from the Office of Inspector General, U.S. Department of Health & Human Services, which excluded Registrant ''from participation in the Medicare program and any State health program'' for a period of fifteen years based on his state court convictions; and a Final Order of the Oklahoma State Board of Medical Licensure and Supervision (issued on June 21, 1990) which placed him on probation for four years and nine months based on his guilty plea in the state criminal proceeding.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that ''[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 * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making the public interest determination in the case of a practitioner, Congress directed 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 * * * controlled substances.

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

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); (citing *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005)).

The Government did not, however, submit either the MOA, which Registrant entered into with DEA, or any of the applications which it alleged he had materially falsified. Instead, it submitted the MOA that DEA entered into with his wife and an affidavit of an Agency Investigator stating that he had ''received information from'' an Investigator in another office that Registrant's MOA ''was identical'' to his wife's. Affidavit of Diversion Investigator, at 1.

Even accepting this would establish that Registrant settled the Show Cause Proceeding on the same terms as his wife did, his wife's MOA merely stated that an April 21, 2000 Order to Show Cause ''further alleged that on August 13, 1991, September 22, 1994, and again on August 28, 1997, the Respondent materially falsified her renewal applications by failing to disclose that the Board placed her medical license on probation in June 1990.'' MOA, at 2. Continuing, the MOA states: ''The above matters, if proven at an administrative hearing, constitute grounds for revocation of the Respondent's DEA Certificate of Registration, and denial of her pending application for renewal of that registration.'' *Id.* Nowhere in the MOA did Registrant's wife admit to the material falsification allegation. Thus, even if Registrant's MOA imposed the same terms, it is clear that the Government has not proved the allegation that he materially falsified his 1991, 1994, and 1997 applications.

In this matter, while I have considered all of the factors, I conclude that it is not necessary to make findings with respect to factors one (the recommendation of the state licensing board), three (registrant's conviction record) and five (such other conduct which may threaten public health and safety). I find that the Government's evidence with respect to Registrant's experience in dispensing controlled substances (factor two) and his compliance with applicable Federal and State laws related to the distribution and dispensing of controlled substances (factor four) makes out a *prima facie* case that Registrant has committed acts which render his registration ''inconsistent with the public interest.'' 21 U.S.C. 823(f), 824(a)(4). I will therefore order that his registration be revoked and that his pending application to renew his registration be denied.

Factors Two and Four—Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.; see also* 21 U.S.C. 802(10) (defining the term ''dispense'' as meaning ''to deliver a controlled substance to an ultimate user by, or pursuant to *the lawful order of, a practitioner,* including the prescribing and administering of a controlled substance'') (emphasis added); Okla. Admin. Code 475:30–1–3(a) (''A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice.'').

As the Supreme Court recently explained, ''the [CSA's] prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act ''in the usual course of * * * professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Laurence T. McKinney,* 73 FR 43260, 43265 n.22 (2008); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that physician ''exceeded the bounds of 'professional practice,' '' when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against * * * misuse and diversion''). The CSA generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. *See Kamir Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007).[5]

Under the Oklahoma Board of Medical Licensure and Supervision's rule on the ''[u]se of controlled substances for the management of chronic pain,'' ''[a] medical history and physical examination must be obtained, evaluated and documented in the medical record.'' Okla. Admin. Code 435:10–7–11(1). Moreover, ''[t]he medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse.'' *Id.* The Oklahoma rule also requires, *inter alia,* that a ''physician should discuss the risk and benefits of the use of controlled substances with the patient.'' *Id.* at 435:10–7–11(3).

As found above, on two occasions, Registrant prescribed Darvocet-N 100 mg., a drug which includes propoxyphene, a schedule IV narcotic controlled substance, as well as Xanax (alprazolam) to an OBN Agent acting in an undercover capacity. Notably, during the first visit, Registrant did not ask the Agent whether she had any medical complaints. Rather, after engaging in small talk and asking for her address, Registrant asked the Agent: ''So what do you want me to put you on?'' While the Agent stated Xanax 2 mg, and told her she had been getting it from another doctor, Registrant did not even ask her if she had anxiety.

Moreover, Registrant then asked the Agent: ''what else are you taking?'' After the Agent replied that she ''was taking Darvocet too,'' Registrant asked: ''I think, are you having some pain?'' While the Agent replied: ''[e]very once in a while,'' Registrant did not ask the Agent any questions regarding ''the nature and intensity of the pain,'' the ''effect of the pain on [the Agent's] physical and psychological function,'' whether the Agent had been previously treated for pain, or whether she had a ''history of substance abuse'' as required under the Oklahoma rule. *See* Okla. Admin. Code 435:10–7–11(1). Moreover, while under the Oklahoma rule a physical examination must ''be obtained,'' the transcript of the undercover visit contains no indication that Registrant performed a physical examination and developed a diagnosis. *See id.* I thus conclude that at the Agent's first visit, Registrant failed to establish a doctor-patient relationship with her. I further conclude that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax and Darvocet-N to her and thus violated Federal law. *See* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

The Xanax and Darvocet prescriptions Respondent gave the Agent at her second visit also violated Federal law. While at this visit, Registrant, after being told by the Agent (who was seeking an even larger quantity of the drug and was three weeks early in seeking the refill) that she had run out of Xanax, did discuss with her that she should not take more of the drug than he prescribed and explained that the drug is controlled ''because people have a tendency to'' take more than is prescribed, once again, he did not determine that the Agent had anxiety or another medical condition that might warrant a prescription for the drug.

Likewise, after telling the Agent to only take the Xanax three times per day, he then asked her if she ''still need[ed]

[5] However, on October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law. 110–425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance ''by means of the Internet without a valid prescription,'' and defines, in relevant part, the ''[t]he term 'valid prescription' [to] mean[] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient.'' 122 Stat. 4820 (codified at 21 U.S.C. 829(e)(1) & (2)). Section 2 further defines ''[t]he term 'in-person medical evaluation' [to] mean[] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.'' *Id.* (codified at 21 U.S.C. 829(e)(2)(B)). These provisions do not, however, apply to Respondent's conduct.

the Darvocet?'' The Agent answered ''yes,'' but Registrant did not even ask her if she had pain, let alone ask her any questions regarding the nature and intensity of the pain, whether the Darvocet was helping to alleviate her pain, or how the pain was affecting her physical and psychological function. Accordingly, with respect to the Agent's second visit, I again conclude that Registrant failed to establish a doctor-patient relationship with her. I also conclude that Registrant lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax and Darvocet-N to her and violated Federal law. *See* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

As the forgoing demonstrates, Registrant has committed acts which ''render his registration * * * inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I will therefore order that his registration be revoked and that any pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as by 28 CFR 0.100(b), I hereby order that DEA Certificate of Registration, BF7430781, issued to Joe C. Fermo, M.D., be, and it hereby is, revoked. I further order that any pending application of Joe C. Fermo, M.D., to renew or modify his registration be, and it hereby is, denied. This Order is effective September 19, 2011.

Dated: August 5, 2011.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ideal Pharmacy Care, Inc., D/B/A Esplanade Pharmacy; Revocation of Registration

On November 12, 2010, I, the then Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy (Registrant), of New Orleans, Louisiana. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration FF1125651, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, on the ground that it has committed acts which render its registration ''inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)). The Show Cause Order also proposed the denial of any pending applications to renew or modify Registrant's registration. *Id.*

The Show Cause Order specifically alleged that on October 14, 2010, investigators conducted an accountability audit of Registrant and found that it had ''significant shortages'' of various controlled substances. *Id.* The Order alleged that these included shortages of: (1) 3,891 dosage units of hydrocodone 7.5/650 mg, 78 percent of the accountable total; (2) 27,179 dosage units of hydrocodone 7.5/750 mg, 59 percent of the accountable total; (3) 5,514 dosage units of hydrocodone 10/500 mg, 48 percent of the accountable total; (4) 114,826 dosage units of hydrocodone 10/650 mg, 96 percent of the accountable total; (5) 83,254 dosage units of alprazolam 2 mg, 96 percent of the accountable total; and (6) 1,616,420 ml of promethazine with codeine, 99 percent of the accountable total. *Id.* at 1–2. Based on the audit results, the Order alleged that the Registrant had violated 21 U.S.C. 827(a)(3) and 842(a)(5), as well as 21 CFR 1304.03, 1304.04, and 1304.21. *Id.* at 2.

Next, the Show Cause Order alleged that various distributors make deliveries of controlled substances to Registrant when it ''is closed,'' and that the ''deliveries are received and signed for by'' non-employees who work ''at the grocery store in which [it] is located,'' and that the deliveries are then ''diverted in violation of 21 U.S.C. 843(a)(3).'' *Id.* The Order thus alleged that Registrant ''has failed to provide effective controls'' against theft and diversion of controlled substances. *Id.* (citing 21 CFR 1301.71).

The Show Cause Order also alleged that Registrant had violated a Memorandum of Agreement (MOA) it entered into with DEA. *Id.* The Order alleged that in the MOA, Registrant agreed that it would not employ its former owners ''in any capacity relating to [its] business,'' and that it would not permit its former owners to have ''access to any area of [it] where controlled substances are kept, stored, or maintained.'' *Id.* The Order alleged that Registrant ''has permitted [its former owners] to enter the pharmacy where controlled substances are present in violation of'' the MOA and 21 CFR 1301.72(d). *Id.*

Based on the matters set forth above, I concluded that Registrant's continued registration during the pendency of the proceeding would constitute ''an imminent danger to public health and safety.'' *Id.* (citing 21 U.S.C. 824(d)). I, therefore, ordered the immediate suspension of Registrant's registration. *Id.*

On November 17, 2010, the Order to Show Cause and Immediate Suspension of Registration, which also notified Registrant of its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing either, and the consequences for failing to do either, *id.* at 3 (citing 21 CFR 1301.43(a) & (c)), was personally served on Registrant's Pharmacist-in-Charge. GX 2. Since the date of service of the Order, more than thirty days have now passed, and neither Registrant, nor anyone purporting to represent it, has requested a hearing or submitted a written statement. Accordingly, I find that Registrant has waived its right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(a), (c) & (d). I, therefore, issue this Decision and Final Order based on relevant material contained in the record submitted by the Government. 21 CFR 1301.43(e).

Findings

Registrant is the holder of DEA Certificate of Registration FI1125651, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 1400 Esplanade Ave., New Orleans, Louisiana. Registrant's registration does not expire until November 30, 2011. Registrant is apparently located in a building which also contains a grocery store. Affidavit of DI, at 8 (GX 22).

On October 14, 2010, DEA Investigators conducted an audit of Registrant's handling of controlled substances. *Id.* at 9. The audit covered the period of October 22, 2008, on which date Registrant had no controlled substances on hand, through the beginning of business on October 14, 2010, at which time the closing inventory for the audit was taken. *Id.* According to the DI, she obtained invoices provided by Registrant's suppliers to determine the total amount of the controlled substances it had purchased during the audit period and was accountable for; the DI also obtained Registrant's records (including the prescriptions on file), as well as data from the state's prescription monitoring program showing the pharmacy's dispensings, and added the amount of its dispensings to the closing inventory to determine the total amount of each drug which it could account for. *Id.* Upon comparing the two amounts, the DI found that Registrant had large