(*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50).

By order of the Commission.
Issued: November 14, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–27666 Filed 11–18–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On November 13, 2013, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Louisiana in the lawsuit entitled *The United States and The State of Louisiana* v. *The City of Shreveport, Louisiana,* Case No: 5:13–cv–03065. The Consent Decree resolves the claims of Plaintiffs in the complaint against The City of Shreveport, for Shreveport's sanitary sewer overflows in violation of Sections 301 and 309 of the Clean Water Act, 42 U.S.C. 1311 and 1319, and the terms and conditions of Louisiana Pollutant Discharge Elimination permits issued to the City under Section 402 of the Clean Water Act, 42 U.S.C. 1342. Under the proposed Consent Decree, Shreveport has agreed to pay a civil penalty of $650,000 and perform remediation of its wastewater collection treatment system, including the Lucas and North Regional treatment plants, estimated to cost approximately $141 million.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *The United States and the State of Louisiana* v. *The City of Shreveport, Louisiana,* DJ#: 90–5–1–1–2767/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $36.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Thomas P. Carroll,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2013–27674 Filed 11–18–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Wheatland Pharmacy; Decision and Order

On July 17, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Wheatland Pharmacy (Applicant), of Dallas, Texas. The Show Cause Order proposed the denial of Applicant's pending application for a DEA Certificate of Registration as a retail pharmacy on the ground that its registration ''would be inconsistent with the public interest,'' as defined in 21 U.S.C. 823(f). GX 7, at 1.

The Show Cause Order alleged that on September 29, 2010, the Administrator issued an Order to Show Cause and Immediate Suspension of Registration to Applicant, and that, on January 18, 2011, Applicant voluntarily surrendered its previous registration. *Id.* at 1–2. Specifically, the Show Cause Order alleged that Lynn Michelle Clark, Applicant's owner/pharmacist, ''unlawfully filled numerous fraudulent controlled substance prescriptions for individuals known to divert these drugs,'' and that she ''knew or should have known that these prescriptions were fraudulent.'' *Id.* at 1. The Show Cause Order further alleged that ''Ms. Clark failed to fulfill her responsibility to dispense controlled substances only pursuant to a prescription issued for a legitimate medical purpose in the usual course of professional practice'' and that she ''also violated federal law by delivering prescriptions for controlled substances to persons who were not the ultimate users of the controlled substances.'' *Id.* at 1–2 (citing 21 U.S.C. 829, 841(a)(1), 842(a) and 802(10) & (27)). Finally, the Order alleged that on July 7, 2011, Ms. Clark submitted an application for a new registration on Applicant's behalf.[1] *Id.* at 1.

Thereafter, Applicant apparently requested a hearing on the allegations and the matter was placed on the docket of the Office of Administrative Law Judges. However, on October 4, 2012, Applicant moved for a stay of the proceeding pending action on its request to withdraw its application, and on October 5, 2012, the ALJ granted the motion. GX 14, at 1.

On November 7, 2012, the Deputy Assistant Administrator, Office of Diversion Control, denied Applicant's request to withdraw. GX 13, at 1. Thereafter, on November 26, 2012, Applicant filed with the ALJ a letter waiving its right to a hearing, citing 21 CFR 1301.43(e). GX 13, at 3. The next day, the ALJ found that Applicant had waived its right to a hearing; the ALJ thus lifted the stay of the proceeding and ordered that the proceeding be terminated. GX 14.

On June 12, 2013, the Government filed a Request for Final Agency Action and the Investigative Record with this Office. Req. for Final Agency Action, at 14. Therein, the Government requests that I deny Applicant's pending

[1] The Show Cause Order also notified Applicant of its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequences for failing to do so. *See* 21 CFR 1301.43.

application for a DEA Certificate of Registration. Based on Applicant's November 26, 2012 letter waiving its right to a hearing, I find that Applicant has waived its right to a hearing and issue this Decision and Final Order based on the Investigation Record submitted by the Government. 21 CFR 1301.43(e). I make the following factual findings.

Findings

Applicant is a pharmacy located at 3207 Kirnwood Drive, Suite 116, Dallas, Texas, which is owned and operated by Lynn Michelle Clark, a registered pharmacist. GX 3; *see also* GX A. On August 12, 2009, the Texas State Board of Pharmacy (TSBP) issued an order suspending Applicant's license for one year; however, the suspension was then probated subject to Applicant's compliance with the terms of the order.[2] GX 1, at 3.

On November 3, 2009, a DEA Diversion Investigator (DI) conducted a pre-registration investigation of Applicant. GX B, at 2. On November 13, 2009, Applicant was issued DEA Certificate of Registration FW1734309, which authorized it to dispense controlled substances in schedules II through V as a retail pharmacy. GX 2.

The 2010 Investigation

On May 7, 2010, Ms. Clark contacted the DEA-Dallas Field Division to report that the day before, a van arrived at Applicant carrying approximately twenty-seven (27) persons, each of whom presented prescriptions for the same three controlled substances: hydrocodone, alprazolam, and promethazine with codeine syrup. GX B, at 2. These prescriptions were all purportedly issued by a Physician's Assistant (PA) who worked for a medical clinic in Houston, Texas, approximately 239 miles away. *Id.; see also* GX C, at 2. Ms. Clark filled all of these prescriptions. GX C, at 2.

Ms. Clark also reported that on May 7, another twenty (20) persons had arrived in a van and presented prescriptions, which were also purportedly issued by the same PA and were for the same controlled substances. *Id.* Ms. Clark also stated that she filled all of these prescriptions, although several days later, she claimed that she had yet to fill some of them. *Id.* at 2–3; *see also* GX B, at 2.

Ms. Clark told a DEA Diversion Investigator (DI) that she had contacted the PA and was told that the prescriptions were valid. GX B, at 2–3. However, the DI later determined that Ms. Clark's statement was false. *Id.* at 3. During the conversation, the DI advised Ms. Clark that ''she could decline to fill such prescriptions'' and also reminded her ''of a pharmacy's corresponding responsibility'' under the Controlled Substances Act. *Id.*

On May 10, 2010, a DEA Special Agent (SA) and a Task Force Officer (TFO) interviewed Ms. Clark at Applicant. GX C, at 2. According to the SA's affidavit, Ms. Clark ''chang[ed] her story several times'' and ''finally admitted that all of the prescriptions . . . purportedly issued by the PA had been brought to the pharmacy from May 5 through May 7, 2010, not by individual patients, but by one individual later identified'' by the alias of SF. *Id.* Ms. Clark claimed that she verified the validity of the prescriptions with personnel at the PA's office. *Id.* Ms. Clark further said that she had not filled all of the prescriptions which SF had presented to her because she had to order the drugs;[3] she was then instructed by the SA ''to fill some of the prescriptions,'' so that law enforcement could monitor SF's activities. *Id.* at 2–3.

On May 14, 2010, the SA and TFO returned to Applicant. *Id.* at 3. Ms. Clark informed the SA and TFO that the day before, KD, a known associate of SF, had presented additional controlled substance prescriptions (for alprazolam and either promethazine or hydrocodone), which were also purportedly issued by the PA, but that she did not fill those prescriptions.[4] *Id.* Ms. Clark stated that she had again called the Houston clinic, and on this occasion, spoke to the PA, who told her that the prescriptions were fraudulent. *Id.* According to the SA, Ms. Clark was then told not to fill any further prescriptions from the clinic. *Id.*

On June 23, 2010, Agents from DEA and TSBP executed a search warrant at Applicant. *Id.* at 4. DEA seized numerous prescriptions for controlled substances which were purportedly issued by the aforementioned PA. *Id.*

The Government submitted evidence of prescriptions for fifteen different patients, all of which were purportedly issued by the PA at the Houston-based clinic, located 239 miles from Applicant. *See generally* GX 6. Each prescription was pre-printed with the clinic name, address, phone and fax numbers, the names of a physician and the PA, and both practitioners' DEA and Texas Department of Public Safety registration numbers. *See id.* On each prescription, the PA's name was checked, indicating that she was the prescribing practitioner. *Id.* A review of the patients' addresses shows that all of them resided in the Dallas metropolitan area, at least 230 miles from the Houston clinic, and that thirteen of the patients lived more than fourteen (14) miles from Applicant. *Id.;* GX C, at 4. For example, one prescription lists the patient's address as: 2400 Skyline Dr., Dallas TX, 75149; this address is 253 miles from the Houston clinic, and 22 miles from Applicant. GX 6, at 66.

As part of the record, the Government submitted evidence showing that on May 5 and 6, 2010, Applicant filled the following prescriptions for twenty-four controlled substances, each of which was purportedly issued by the PA at the Houston clinic on May 4, 2010:

1. For SF: 120 Lortab 10/500 mg (hydrocodone/acetaminophen, a schedule III controlled substance), 240 ml of promethazine/codeine syrup (a schedule III controlled substance), and 90 Xanax 2 mg (a schedule IV controlled substance), along with amoxicillin (a non-controlled drug), for a stated diagnosis of chronic pain/anxiety/bronchitis. GX 6, at 3.

2. For BJW: 120 Norco 10/325 mg (hydrocodone and acetaminophen), 240 ml promethazine/codeine, and 90 Xanax 2 mg, as well as folic acid, for chronic pain/anxiety/bronchitis. *Id.* at 8.

3. For WH: 120 Lortab 10/500 mg, 240 ml promethazine/codeine, 90 Xanax 2 mg, along with Lovastatin (a non-controlled drug), for chronic pain/anxiety/bronchitis. This prescription bore a handwritten note stating: ''verified Michael Reed, RN.'' *Id.* at 15.

4. For HL: 120 Norco 10/325 mg, 240 ml promethazine/codeine, 90 Xanax 2 mg, along with Pravastatin (a non-controlled drug), for chronic pain/anxiety/bronchitis. *Id.* at 20.

5. For LY: 120 Lortab 10/500 mg, 240 ml promethazine/codeine, 90 Xanax 2 mg, and amoxicillin, again for chronic pain/anxiety/bronchitis. *Id.* at 25.

6. For DSD: 120 Norco10/325 mg, 240 ml promethazine/codeine, 90 Xanax 2 mg, and Lovastatin, for chronic pain/anxiety/bronchitis. *Id.* at 30.

7. For SJ: 120 Lortab 10/500 mg, 240 ml promethazine/codeine, 90 Xanax 2 mg, and folic acid for chronic pain/anxiety/bronchitis. *Id.* at 37. This prescription also bore a handwritten

[2] The basis for the order was a deferred adjudication in 1991 following Ms. Clark's guilty plea to a felony charge of Theft of Service in the District Court of Harris County, Texas. The record does not reflect why TSBP waited 18 years to issue the probationary order. The order required Applicant to ''obey . . . all Federal laws and laws of the State of Texas with respect to pharmacy, controlled substances, [and] dangerous drugs.'' GX 1, at 3.

[3] The record, however, is not clear as to how many of the prescriptions she had filled at the time of the May 10 interview.

[4] None of these prescriptions are in the record.

note stating: ''RX & PA verified by Shaquanna @ (713) 799–9400 same address.'' However, the pre-printed phone number on the prescription is (832) 236–5688.[5] *Id.*

A patient profile from Applicant also establishes that on May 5 and 6, 2010, Ms. Clark dispensed to LH 120 hydrocodone/apap 10/500 mg, 240 ml promethazine/codeine syrup, and 90 alprazolam 2 mg, along with Lovastatin, with the same PA's name listed as the doctor. *Id.* at 40. However, the record contains neither a prescription nor labels for these medications.

The record includes evidence including prescriptions,[6] pharmacy labels, and patient profiles establishing that between June 9 and 12, 2010, Respondent dispensed additional prescriptions, which were also purportedly issued by the same Houston-based PA for eleven persons. *See generally* GX 6. The evidence shows that Respondent dispensed a total of thirty-three controlled substances, specifically for 120 Lortab 10/500 mg, 240 ml promethazine/codeine, and 90 Xanax 2 mg.[7] *See id.* at 13, 18, 35, 42, 47, 52, 57, 62, 66, 71, 74. These prescriptions were issued to patients WH, VH, SJ, LFH, SD, EC, HJ, JM, BJR, KJ, and FW; each of the prescriptions listed the same three diagnoses of chronic pain/anxiety/bronchitis.[8] *See id.; see also id.* at 12, 34, 42, 46, 51, 61, 66–A, 70, 74.

Ms. Clark filled the June 2010 prescriptions after she told the SA that the PA had personally informed her that the prescriptions were fraudulent. Moreover, Ms. Clark filled the prescriptions, notwithstanding that the SA had previously told her to stop filling the PA's prescriptions. GX C, at 4; GX 6, at 11–22, 33–77.

A TSPB Investigator presented copies of the above-referenced prescriptions and other records from Applicant to the PA at the Houston clinic for her review. GX A, at 3. After reviewing these records, the PA provided affidavits wherein she stated that she ''did not write a prescription for, call in . . . or by any other means cause the authorization for'' each patient listed above. *Id.; see also* GX 6, at 4, 9, 16, 21, 31, 38, 43, 48, 53, 58, 63, 67, 72, 76.

The Accountability Audit

During the execution of the search warrant, the DI, along with TSPB investigators, conducted a closing inventory of controlled substances. GX B, at 3. In her affidavit, the DI stated that Ms. Clark signed the closing inventory sheet attesting to its accuracy, and that she later used that inventory in an accountability audit she conducted of Applicant's handling of six hydrocodone products from November 13, 2009 through June 23, 2010. *Id.* According to the DI's affidavit, each of the audited drugs had a shortage or overage, with some types (notably hydrocodone 10/500) short as many as 4,000 tablets. *Id.; see also* GX 12. However, the Government made no allegation in the Show Cause Order based on the results of the accountability audit and I therefore do not consider any of this evidence. *See Kenneth Harold Bull,* 78 FR 62666, 62674 (2013); *CBS Wholesale Distributors,* 74 F 36746, 36749–50 (2009).

The DI also stated that her review of prescriptions seized from Applicant revealed that it filled controlled substance prescriptions that were not properly executed by the prescribing practitioner (*i.e.,* they lacked physician's DEA registration number, patient address, date prescription issued, etc.) in violation of 21 CFR 1306.05. GX B, at 3. While this evidence may have been relevant on the issue of whether Ms. Clark should have known the PA's prescription were fraudulent, none of the prescriptions were submitted for the record and it is unclear whether any of these prescriptions were issued by the PA. Moreover, to the extent the prescriptions were issued by other prescribers, the Government made no allegation in the Show Cause Order regarding the filling of these prescriptions.[9] *See Bull,* 78 FR at 62674; *CBS Wholesale,* 74 FR at 367449–50. I therefore do not consider any of this evidence.

As noted above, on September 29, 2010, the Administrator issued an Order to Show Cause and Immediate Suspension of Registration (OTSC–ISO) to Applicant. GX 4, at 1–3. On October 4, 2010, Applicant's owner was personally served with the OTSC–ISO, and all controlled substances at Applicant were seized by the DEA Dallas field office. GX C, at 4. The OTSC–ISO specified that Applicant's registration was ''suspended, effective immediately,'' and would remain suspended until a final determination in the matter was reached. GX 4, at 3. On January 18, 2011, Applicant voluntarily surrendered its registration. GX 5; *see also* Certified Registration History, GX 2.

On July 7, 2011, Applicant re-applied for a registration. GX 3.

The 2012 Investigation

On August 14, 2012, DEA was alerted by the Pharmacy Buying Association (PBA), a pharmaceutical distributing company, that Applicant ordered 1,000 tablets of carisoprodol, a schedule IV controlled substance in Texas,[10] on December 1, 2010, December 27, 2010, and February 15, 2011. GX C, at 5. Based on this information, an SA accessed the Texas prescription monitoring data for this period and discovered that Applicant had dispensed controlled substances on ten occasions after its DEA registration was suspended on October 4, 2010. *Id.* Specifically, the SA found that Applicant made the following dispensings:

Date	Drug and schedule
Oct. 7, 2010 ...	propoxyphene napsylate (sch. IV)
Oct. 9, 2010 ...	Lyrica (pregabalin, sch. V)
Oct. 9, 2010 ...	Provigil (modafinil, sch. IV)
Oct. 11, 2010	diazepam (sch. IV)
Oct. 19, 2010	clonazepam (sch. IV)
Oct. 19, 2010	Lyrica
Oct. 26, 2010	hydrocodone (sch. III)
Oct. 26, 2010	propoxyphene napsylate (two prescriptions)
Oct. 27, 2010	lorazepam (sch. IV)

GX C, at 5.

[5] Also in evidence for each of the prescriptions discussed above, with the exception of the prescriptions for LH, is the pharmacy label for each medication. GX 6, at 2, 7, 14, 19, 24, 28, 36.

[6] The prescriptions for Patient VH and FW were missing. However, the pharmacy's patient profile for VH establishes that on June 9, 2010, Applicant dispensed hydrocodone, alprazolam, and promethazine with codeine based on a prescription purportedly issued to her by the PA. GX 6, at 18. With respect to FW, both the patient profile and the pharmacy labels establish that on June 12, 2010, Applicant dispensed the same three drugs based on a prescriptions purportedly issued to him by the PA. GX 6, at 74–75.

[7] In his affidavit, the SA stated that the above-referenced combination of hydrocodone, alprazolam and promethazine with codeine syrup is known in the Dallas area as an illicit drug cocktail that is commonly abused and/or diverted by drug seekers and individuals involved in the trafficking of controlled substances. GX C, at 2. However, no evidence establishes why a pharmacist would know this.

[8] The names of four of the purported patients (WH, HL, SJ, and LFH) had been previously used on the prescriptions which were presented in May.

[9] The DI also stated that Applicant commingled controlled substance prescriptions with non-controlled substance prescriptions. GX B, at 3. Because the Show Cause Order contains no allegation based on this assertion, I do not consider this evidence.

[10] Carisoprodol was scheduled as a Schedule IV controlled substance by the Texas Legislature in June 2009. *See* 2009 Tex. Sess. Law Serv. Ch. 774 (S.B. 904) (codified in Tex. Health & Safety Code Ann. § 481.037). However, there is no evidence in the Investigative Record that Applicant did not hold a Texas controlled substance registration when it obtained these drugs and the rule placing carisoprodol into Schedule IV of the CSA did not take effect until January 11, 2012. *See* DEA, *Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV,* 76 FR 77330 (2011).

On August 30, 2012, the Texas Department of Public Safety (DPS) performed a registrant inspection of Applicant. GX A, at 3. The state inspector found that on October 4, 2010, Applicant had dispensed 30 capsules of Lyrica. *Id.* However, it is unclear whether the dispensing occurred before or after the ISO was served.[11]

Later that day, a state search warrant was executed at Applicant by local law enforcement entities and DEA personnel. GX C, at 6. During the search, the officers seized prescription vials labeled as containing hydrocodone, propoxyphene napsylate, lorazepam and Lyrica, pharmacy receipt labels, prescriptions for controlled substances, and controlled substance dispensing records. *Id.; see also* GX 8. The vials were affixed with labels from both Applicant and other Dallas pharmacies.[12] GX 8, at 2; GX C, at 7.

During the search, the Officers found controlled substance prescriptions from various doctors on Applicant's fax machine. GX C, at 8. When asked about the prescriptions, Ms. Clark asserted that she transferred them to other pharmacies to fill, and that she would sometimes bring the filled controlled-substance prescriptions back to Applicant and put them with the non-controlled substance prescriptions to be dispensed or delivered. *Id.* Ms. Clark also stated that on some occasions, patients came into Applicant to pick up their controlled and non-controlled substance prescriptions. *Id.* The Government did not, however, provide copies of the prescriptions nor identify how many it found; nor did it produce any evidence regarding the veracity of Ms. Clark's statement that she sent the prescriptions to other pharmacies for filling.

In his affidavit, the SA stated that Applicant was dispensing controlled substances to clients classified as home healthcare service providers through August 2012. GX C, at 8. He also stated that he had interviewed the program director and medical assistant at BCA, a home healthcare provider, and was told that Applicant ''delivered controlled substances to BCA for dispensing to BCA's clients,'' and that it ''was the sole provider of all prescriptions filled for BCA.'' [13] *Id.*

During the interview, BCA's medical assistant showed the SA a prescription blister pack for 60 tablets of lorazepam .5mg; the label affixed to the pack establishes that Applicant dispensed the drugs on August 1, 2012. *See* GX C, at 8–9; GX 9, at 1–2. The medical assistant also showed the SA a second blister pack, which originally contained 60 tablets of clonazepam 1 mg; its label establishes that Applicant dispensed the drugs on August 28, 2012. GX C, at 8–9; GX 9, at 3–5.

Discussion

Pursuant to section 303(f) of the Controlled Substances Act (CSA), ''[t]he Attorney General may deny an application for [a practitioner's] registration . . . if the Attorney General determines that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f); *see also id.* § 802(21) (defining ''[t]he term 'practitioner''' to include a pharmacy). In making the public interest determination, 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.

Id.

''These factors are to be considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 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 . . . an application for registration [should be] denied.'' *Id.; see also Kevin Dennis, M.D.,* 78 FR 52787, 52794 (2013); *MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2010). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009) (quoting *Hoxie,* 419 F.3d at 482)).[14]

The Government has the burden of proving, by substantial evidence, that grounds exist to deny the application pursuant to 21 U.S.C. 823(f). 21 CFR 1301.44(d). This is so even in a non-contested case.

Having considered all of the factors, I conclude that the Government's evidence with respect to Applicant's experience in dispensing controlled substances (factor two) and its compliance with applicable state and federal laws relating to controlled substances (factor four), establishes a *prima facie* case that issuing it a new registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Because Applicant waived its right to present evidence in refutation of the Government's *prima facie* case, I will order that its application be denied.

Factor 1: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority

Applicant currently holds a pharmacy license issued by the Texas State Board of Pharmacy and a Controlled Substance Registration issued by the Texas Department of Public Safety. As found above, in 2009 the TSBP issued an Order suspending Applicant's license on the basis of a felony offense of theft of services in 1991. The Board then probated the suspension, conditioned

[11] There is a conflict in the statements of the Government's witnesses as to whether this prescription, which was issued on October 4, 2010, was dispensed on that date or on October 9, 2010. *Compare* GX A, at 3; *with* GX C, at 5–6. However, there is no evidence that either affiant participated in the DPS's Inspection and both affiants apparently relied on the hearsay statement of the DPS Investigator. As the Government has the burden of proving its allegations by a preponderance of the evidence, and it has provided no further evidence to resolve the dispute, to the extent this evidence was offered to support a finding that Applicant dispensed a controlled substance after it was served with the ISO, I place no weight on it.

[12] When asked why she continued to possess controlled substances, Ms. Clark ''stated that DEA must have left the drugs on the premises when they seized [her] controlled substances on October 4, 2010.'' GX C, at 7–8.

[13] Also included in the record is a signed statement by the BCA program director stating that she ''has seen the pharmacist drop of [sic] medication to this office from Wheatland Pharmacy. I have seen Michelle drop of [sic] medication from Wheatland Pharmacy.'' GX 10. However, this statement does not indicate whether the delivered medication included controlled substances. Moreover, while the statement was witnessed by an SA and TFO, it does not include an attestation clause.

However, the record also includes a statement from the Medical Assistant. GX 11. Therein, the Medical Assistant stated that ''since [she] returned to the Grand Prairie office on May 1st 2012, all the medications received from Wheatland pharmacy, all had labels from Wheatland pharmacy, controlled and non-controlled medications.'' *Id.* The Medical Assistant also stated that when Applicant delivered drugs, she would review the medications to make sure that it was the correct drug for each patient. *Id.* This statement was also witnessed by an SA and TFO, and contained an attestation clause. *See id.* at 2. I therefore find that it constitutes substantial evidence that Applicant continued to dispense controlled substances when it did not possess a DEA registration.

[14] ''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *See MacKay,* 664 F.3d at 821.

upon Applicant complying with the terms of the order, including that it comply with by all federal and state laws ''with respect to pharmacy, controlled substances, dangerous drugs,'' as well as ''all rules and regulations adopted pursuant to the above-mentioned statutes.'' GX 1, at 3. The Government has provided no additional evidence that since 2009, either the TSBP or TDPS have taken action either against Applicant's pharmacy license or its state controlled substance registration. GX A.

DEA has long held, however, that a State's failure to take action against an applicant's pharmacy license or controlled substance registration (where such registration is also required) is not dispositive in determining whether the continuation of a registration is in the public interest. *East Main Street Pharmacy,* 75 FR 66149, 66162 n.47 (2010); *Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75967 (2000). ''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Mortimer Levin,* 57 FR 8680, 8681 (1992). Thus, while there is no evidence that the Texas Board has revoked Applicant's pharmacy license or its state registration, DEA has repeatedly held that while a practitioner's possession of state authority constitutes an essential condition for obtaining and maintaining a registration, *see* 21 U.S.C. 802(21) & 823(f); it '' 'is not dispositive of the public interest inquiry.' '' *George Mathew,* 75 FR 66138, 66145 (2010), *pet. for rev. denied Mathew* v. *DEA,* No. 10–73480, slip op. at 5 (9th Cir., Mar. 16, 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie,* 68 FR 15227, 15230 (2003). Thus, this factor is not dispositive either for or against the issuance of a registration to Applicant. *See Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 74 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).[15]

Factors Two and Four: The Applicant's Experience in Dispensing Controlled Substances and Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is unlawful unless it has been ''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 while ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . *a corresponding responsibility rests with the pharmacist who fills the prescription.'' Id.* (emphasis added). Continuing, the regulation states that ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription . . . and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*[16]

DEA has consistently interpreted this provision ''as prohibiting a pharmacist from filling a prescription for a controlled substance when [s]he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.''' *Medicine Shoppe-Jonesborough,* 73 FR 364, 381, *pet. for rev. denied, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appd'x. 409, 412 (6th Cir. 2008) (quoting *Medic-Aid Pharmacy,* 55 FR 30043, 30044 (1990)); *see also Frank's Corner Pharmacy,* 60 FR 17574, 17576 (1995); *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990); *United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980). This Agency has further held that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close [her] eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted). The regulation thus ''requires . . . pharmacists [to] use common sense and professional judgment.'' *Id.*

Similarly, under the TSBP's regulations, a pharmacist is required to ''exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed.'' 22 Tex. Admin. Code § 291.29(a). Moreover, ''[a] pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued without a valid pre-existing patient-practitioner relationship.'' *Id.* § 291.29(b). The TSBP's regulations identify various ''[r]easons to suspect that a prescription may have been authorized in the absence of a valid patient-practitioner relationship,'' including, *inter alia:* ''(1) The number of prescriptions authorized on a daily basis by the practitioner; (2) the manner in which the prescriptions are . . . received by the pharmacy; [and] (3) [t]he geographical distance between the practitioner and the patients.'' *Id.* § 291.29(c)(1)–(3).

Here, the evidence shows that Ms. Clark, Applicant's owner and pharmacist, clearly knew or had reason to know that the prescriptions presented on May 6, 2010 by SF, which were purportedly issued by the Houston-based PA for some twenty-seven patients, each of whom received the same three controlled substances (hydrocodone/acetaminophen, promethazine with codeine cough syrup, and alprazolam), were not issued for a legitimate medical purpose. 21 CFR 1306.04(a). Ms. Clark had ample reason to know that the prescriptions were not legitimate given that the PA, whose prescription pad had been used, practiced in Houston, approximately 240 miles from Applicant; each of the persons received the same combination of controlled substances; and Ms. Clark eventually admitted that all of the prescriptions had been brought to Applicant by SF. Ms. Clark nonetheless filled the prescriptions.[17] Moreover,

[15] As for factor three—the Applicant's Record of Convictions of Offenses Related to the Manufacture, Distribution, or Dispensing of Controlled Substances—it is noted that the TSBP's 2009 Order was based on a 1991 felony conviction of Ms. Clark for theft of services. GX 1, at 1. However, the Government does not contend that this offense falls within factor three. Moreover, there is no evidence that either Applicant or Ms. Clark has been criminally charged, let alone convicted of, any of the misconduct established on this record. Accordingly, consistent with DEA precedent, I find that this factor neither weighs in favor of, or against a determination that Applicant's registration ''would be inconsistent with the public interest.'' 21 U.S.C. § 823(f). *See also Dewey C. MacKay,* 75 FR 49956, 49973 (2010); *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007).

[16] To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales v. Raich,* 545 U.S. 1, 13 (2005). As the Supreme Court has explained, the prescription requirement, 21 CFR 1306.04(a), advances this purpose by ''ensur[ing that] 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)).

[17] In *East Main Street Pharmacy,* the Administrator noted the following examples of red flags, including the respective locations of the patients and prescriber and that patients were travelling long distances to both obtain the prescriptions and fill them (and were bypassing numerous pharmacies en route), the lack of individualization of dosing, and that the patients were obtaining the same combination of multiple controlled substances. 75 FR 66149, 66157–59 & 66164 (2010).

while Ms. Clark claimed to DEA Investigators that she had verified the prescriptions with the PA's office, the Investigators ultimately determined that she did not do so. I thus hold that Ms. Clark violated federal law by filling each of these prescriptions. 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a).

The following day, Ms. Clark again violated federal law by filling at least some of prescriptions for the same three controlled substances, which were purportedly issued in the name of twenty persons by the same Houston-based physician's assistant, whose prescriptions she filled the day before. Here again, the prescriptions were presented to Ms. Clark by SF, and here again, Ms. Clark falsely claimed that she verified the prescriptions with the PA's office. While Ms. Clark subsequently stated that she had not filled all of the prescriptions, she admitted to filling some of them. I thus hold that Ms. Clark violated federal law with respect to those prescriptions she did fill. 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a).[18]

On May 14, 2010, Ms. Clark told Investigators that the day before, KD, a known associate of SF, had brought in additional controlled substance prescriptions for alprazolam and either promethazine or hydrocodone, which were also purportedly issued by the same Houston-based PA. GX C, at 3. Ms. Clark told the Investigators that she did not fill the prescriptions because she had actually spoken with the PA and was told that the prescriptions were fraudulent. Moreover, during the interview, Ms. Clark was told not to fill any further prescriptions from the PA's clinic.[19]

Notwithstanding that Ms. Clark had been told by the PA that the prescriptions that were being presented at her pharmacy were fraudulent (and had also been told by a DEA Agent not to fill them)—as if she needed to be told, given the circumstances of a single person presenting on multiple days, prescriptions for multiple controlled substances for more than forty patients, all of which were purportedly issued by a PA located nearly 240 miles away—she proceeded to fill additional prescriptions which were purportedly issued by the PA. *See* GX C, at 4; *see generally* GX 6. As the evidence shows, on or about June 9, 2010, Ms. Clark received eleven more prescription forms, which were purportedly issued by the PA and authorized the dispensing of thirty-three additional prescriptions for the same cocktail of hydrocodone, promethazine with codeine, and alprazolam, which she had previously filled. Moreover, some of the prescriptions used the names of the same ''patients'' whose names were used on the fraudulent prescriptions presented by SF to Ms. Clark in early May. Nonetheless, Ms. Clark filled the prescriptions, in abject disregard of her corresponding responsibility under the CSA not to fill clearly fraudulent prescriptions. *See* 21 CFR 1306.04(a).[20] Ms. Clark's filling of the prescriptions is egregious misconduct and supports the conclusion that issuing Applicant a new registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

This, however, is not the only misconduct proved on this record, as there is substantial evidence showing that after Ms. Clark was served with the Immediate Suspension Order on October 4, 2010, she continued to dispense controlled substances and did so notwithstanding that the Order, in addition to its title, clearly stated that it was ''effective immediately.'' GX 4, at 3. More specifically, the evidence shows that Applicant dispensed ten prescriptions for controlled substances between October 7 and October 27, 2010. GX C, at 5. Moreover, the evidence showed that Applicant was still dispensing controlled substances in August 2012, even though Ms. Clark had voluntarily surrendered Applicant's DEA registration in January 2011. *See* GX 5 (Voluntary Surrender form); GX 9 (blister packs for drugs dispensed on August 1 and 28, 2012). Indeed, Investigators found that Applicant was still receiving prescriptions for controlled substances, notwithstanding that the Immediate Suspension Order had been served on Ms. Clark nearly two years earlier.

Under the CSA, it is ''unlawful for any person knowingly or intentionally . . . to use in the course of the manufacture, distribution, or dispensing of a controlled substance . . . a registration number which is revoked [or] suspended.'' 21 U.S.C. 843(a). Also, ''[e]very person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.'' *Id.* § 822(a)(2). Finally, a DEA regulation expressly provides that ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1301.13(a). *See also* 21 U.S.C. 841(a) (''Except as authorized by this subchapter it shall be unlawful for any person knowingly or intentionally to dispense or possess with intent to . . . dispense . . . a controlled substance.'')[21]

Here again, it is clear that Ms. Clark and Applicant flagrantly violated federal law by dispensing controlled substance knowing that she and Applicant lacked authority to do so. While, by itself, Ms. Clark's egregious misconduct in dispensing the fraudulent prescriptions warrants the denial of Applicant's application, Ms. Clark's further misconduct in dispensing controlled substances when she lacked the authority to do so provides an additional basis which supports the conclusion that the issuance of a new registration to Applicant ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Because Applicant waived its right to a hearing or to submit a written statement in lieu of hearing, there is no evidence to the contrary. Accordingly, I will order

[18] However, with respect to those prescriptions she filled based on the instruction of Agency personnel to do so, so that the latter could monitor SF's activities, I do not find that she violated federal law in doing so.

[19] It is noted that on her application, Ms. Clark disputed that she was told not to fill the prescriptions, stating that ''DEA Agents never advised or admonished [her] not to fill the prescriptions.'' GX 3. However, I find credible the statement of the SA that during May 14, 2010 interview, he told her not to fill any further prescriptions from the PA's clinic. GX C, at 3.

[20] The Government also alleged that Applicant and ''Ms. Clark violated federal law by delivering prescriptions for controlled substances to persons who were not the ultimate users of the'' drugs. GX 7, at 2. Because by definition, ''the term 'ultimate user' means a person *who has lawfully obtained,* and who possesses, a controlled substance for his own use or for the use of a member of his household,'' 21 U.S.C. 802(27) (emphasis added), and it is indisputable that all of the PA's prescriptions were fraudulent, the allegation is simply duplicative of the allegation that Ms. Clark dispensed controlled substances when she had reason to know that the prescriptions were fraudulent and thus obviously not issued for a legitimate medical purpose.

[21] While the Government also introduced evidence showing that the Investigators found on Applicant's premises several vials of controlled substances that had been dispensed by other pharmacies to persons other than Ms. Clark, it neither offered evidence establishing that the drugs were tested and found to be a controlled substance, nor evidence showing that the drugs match the physical appearance of the various medications as set forth in the Physicians' Desk Reference. Moreover, the Government offered no evidence showing that the patients listed on the vials were not employees of Applicant.

As for the three purchases of carisoprodol, as found above, all of these purchases occurred before the drug became a federally controlled substance on January 11, 2012. *See* 76 FR 77330. Moreover, while at the time of the purchase, carisoprodol was a schedule IV controlled substance under Texas law, there is no evidence that Applicant did not hold a DPS registration at the time of the purchases. Thus, I do not place any weight on this evidence.

that Applicant's pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) and 28 CFR 0.104, I order that the application of Wheatland Pharmacy, for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. This order is effective immediately.

Dated: November 8, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–27700 Filed 11–18–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Mylan Pharmaceuticals, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on October 7, 2013, Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Methadone (9250)	II
Morphine (9300)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than December 19, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import basic classes of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: November 12, 2013.

Joseph T. Rannazzisi,

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

[FR Doc. 2013–27660 Filed 11–18–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; GE Healthcare

Pursuant to Title 21, Code of Federal Regulations 1301.34(a), this is notice that on September 18, 2013, GE Healthcare, 3350 North Ridge Avenue, Arlington Heights, Illinois 60004–1412, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Cocaine (9041), a basic class of controlled substance listed in schedule II.

The company plans to import small quantities of ioflupane, in the form of three separate analogues of Cocaine that will be used for the support and manufacture of DaTSCAN (ioflupane 1–123) injection for distribution as a radioactive diagnostic imaging agent utilized in the diagnosis of Parkinson's disease.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedules I and II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than December 19, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: November 5, 2013.

Joseph T. Rannazzisi,

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

[FR Doc. 2013–27661 Filed 11–18–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0046]

Agency Information Collection Activities; Existing Collection, Comments Requested: Friction Ridge Cards: Arrest and Institution; Applicant; Personal Identification; FBI Standard Palm Print; Supplemental Finger and Palm Print

ACTION: 30-day Notice of Information Collection for Reinstatement.

The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) Division will be submitting the following information collection renewal to the Office of Management and Budget (OMB) for review in