LIHPRHA (see, in particular, section 222(a)(2)(G)(i), 12 U.S.C. 4112 (a)(2)(G) and HUD's regulations at 24 CFR 248.145(a)(9)) requires that future rent adjustments for LIHPRHA projects be made by applying an annual factor, to be determined by HUD to the portion of project rent attributable to operating expenses for the project and, where the owner is a priority purchaser, to the portion of project rent attributable to project oversight costs.

III. Findings and Certifications

Environmental Impact

This issuance sets forth rate determinations and related external administrative requirements and procedures that do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number for this program is 14.187.

Paperwork Reduction Act

This notice reduces information collection requirements already submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

Dated: September 26, 2014.

Carol J. Galante,

Assistant Secretary for Housing-Federal Housing Commissioner.

Appendix

OPERATING COST ADJUSTMENT FACTORS FOR 2015

Alabama	1.9
Alaska	2.2
Arizona	2.0
Arkansas	1.9
California	2.6
Colorado	2.0
Connecticut	1.7
Delaware	1.5
District of Columbia	2.3
Florida	2.2
Georgia	2.0
Hawaii	1.5
Idaho	2.5
Illinois	1.7
Indiana	2.1
Iowa	2.1
Kansas	2.2
Kentucky	2.1
Louisiana	2.7
Maine	1.8
Maryland	2.1
Massachusetts	2.4
Michigan	1.4
Minnesota	2.4
Mississippi	2.4
Missouri	2.0
Montana	2.2
Nebraska	2.1
Nevada	2.0
New Hampshire	2.2
New Jersey	2.0
New Mexico	2.4
New York	2.2
North Carolina	2.0
North Dakota	2.0
Ohio	2.0
Oklahoma	1.8
Oregon	2.2
Pacific Islands	1.5
Pennsylvania	2.0
Puerto Rico	2.0
Rhode Island	2.7
South Carolina	2.2
South Dakota	2.0
Tennessee	2.0
Texas	2.4
Utah	2.2
Vermont	2.0
Virgin Islands	2.4
Virginia	1.8
Washington	2.2
West Virginia	1.6
Wisconsin	2.1
Wyoming	2.1
US Average	2.1

[FR Doc. 2014–23475 Filed 10–1–14; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 701–TA–457 (Review)]

Certain Tow-Behind Lawn Groomers and Parts Thereof From China

AGENCY: United States International Trade Commission.

ACTION: Notice of termination of five-year review.

SUMMARY: The Commission instituted the subject five-year review in July 2014 to determine whether revocation of the countervailing duty order on certain tow-behind lawn groomers and parts thereof from China would be likely to lead to continuation or recurrence of material injury (79 FR 37349). On September 23, 2014, the Department of Commerce published notice that it was revoking the order effective September 23, 2014, ''{b}ecause the domestic interested parties did not participate in this sunset review . . .'' (79 FR 56769). Accordingly, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), the subject review is terminated.

DATES: *Effective Date:* September 24, 2014.

FOR FURTHER INFORMATION CONTACT: Angela M.W. Newell (202–708–5409), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*).

Authority: This review is being terminated under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.69 of the Commission's rules (19 CFR 207.69).

Issued: September 29, 2014.

By order of the Commission.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014–23460 Filed 10–1–14; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14–01]

The Medicine Shoppe; Decision and Order

On March 24, 2014, Administrative Law Judge Gail A. Randall issued the attached Recommended Decision. Respondent filed Exceptions to the Recommended Decision.

Having reviewed the entire record including Respondent's Exceptions, I have decided to adopt the ALJ's findings of fact, conclusions of law, and recommended order. A discussion of Respondent's Exceptions follows.

Respondent's Exceptions

Respondent raises twelve different exceptions to the ALJ's decision in no logical order. His contentions can be summarized as follows:

(1) That the ALJ failed to consider less punitive sanctions than revocation;

(2) that the ALJ improperly rejected his evidence of remedial measures by requiring him to produce corroborating evidence because she failed to rule on the Government's motion *in limine* and never granted him permission to introduce such evidence;

(3) that the ALJ ''imposed an undefined and vague standard of proof'' on the issue of his remedial measures because she rejected his testimony in the absence of corroborating evidence;

(4) that the ALJ improperly relied on the testimony of the Government's Expert for various reasons and thus made multiple findings which are unsupported by substantial evidence (exceptions 4–6, 8);

(5) that the ALJ's application of the public interest factors is unsupported by substantial evidence and is arbitrary and capricious;

(5) that the ALJ's findings of fact and conclusions of law regarding Respondent's employment of a convicted drug felon are unsupported by substantial evidence;

(6) that the ALJ's findings of fact and conclusions of law regarding Respondent's recordkeeping deficiencies are unsupported by substantial evidence;

(7) that the ALJ's findings of fact and conclusions of law regarding Respondent's audit and inventory deficiencies are unsupported by substantial evidence; and

(8) that his acceptance of responsibility and evidence of remedial measures renders his continued registration consistent with the public interest.

Resp. Exceptions, at 5–26. Notwithstanding the order in which Respondent presents his exceptions, I first address his challenges that the ALJ's findings of various violations are unsupported by substantial evidence.

Challenges to the Substantiality of the Evidence

At the hearing, the Government alleged that Respondent (through its pharmacists) violated its corresponding responsibility under the Controlled Substances Act (CSA) by dispensing prescriptions that lacked a legitimate medical purpose, *see* 21 CFR 1306.04(a), as well as prescriptions that did not comply with 21 CFR 1306.05(a) because they were missing required information such as addresses and/or were not signed by the prescribing practitioner. As support for the allegations, the Government introduced several hundred controlled substance prescriptions, and elicited the testimony of an Expert witness in pharmacy practice.

Respondent asserts that the Government's Expert was not competent to testify as an Expert because, while she teaches a class in pharmacy law, ''on cross-examination . . . she could [not] name the federal and state statutes that govern the standards she applied when rendering her expert opinion.'' Exceptions, at 13. Respondent contends that ''[t]hese are of course the Federal Controlled Substances Act and the Texas Controlled Substances Act found in the Texas Health & Safety Code'' and that ''[i]t defies logic how [she] could be legitimately regarded as an expert in the field of pharmacy law and retail pharmacy.'' *Id.*

It is true that the Expert stated that ''I can't answer that'' when asked what the federal and state statutes were called. However, she then testified that ''It's just federal law and Texas law that we use to apply. For the exact statute or standard number and heading, I cannot recall.'' Tr. 71. And on further questioning, the Expert explained that ''we don't teach the numbers. If you ask most pharmacists, I don't think that they would be able to tell you the statute or the standard number, but they would be able to recite the law to you and how it is applied to pharmacy practice.'' *Id.* Thus, read in its entirety, the transcript shows that the Expert interpreted the question as asking for the specific section numbers of the relevant provisions of the CSA and State law, and not for the name of the respective statutes.

Moreover, Respondent does not identify any testimony on the part of the Expert which is inconsistent with the decisional law of either the courts or this Agency. I thus reject Respondent's Exception (Number Five) that the Government's Expert was not qualified to testify as an Expert in pharmacy law and practice.[1]

Respondent also takes exception to the ALJ's reliance on the Expert's testimony when she found that Respondent violated its corresponding responsibility when it failed to verify the validity of 154 prescriptions it dispensed which presented red flags. Exceptions, at 11–12. According to Respondent, the ALJ should have rejected the Expert's testimony because during cross-examination, it was established that she was provided with ''photocopies of one side of the prescriptions, instead of both sides which included the data she claimed was missing.'' Exceptions, at 12. Moreover, Respondent contends that included in the exhibits was a spreadsheet which listed ''the prescriptions and a description of what finding its expert was to make regarding each prescription.'' *Id.* Respondent then argues that the Expert ''testified she never asked for any other information about the prescriptions and simply endorsed the findings provided to her by the Government'' while its owner ''testified to the resolution of those 'red flags' but his testimony was INEXPLICABLY rejected in favor of [that of] the Government's expert.'' *Id.*

No citations to the record are provided to support Respondent's assertions that the Expert was provided with only one side of the prescriptions. Indeed, the prescriptions submitted for the record include a photocopy of the front of the prescription and the back on which the dispensing labels were placed. *See* Tr. 72–73 (Expert's testimony that the second page of the prescription ''was provided with all of the prescriptions.''). Thus, Respondent's assertion is a blatant mischaracterization of the record.

Nor is there any evidence to support the contention that the Expert ''simply endorsed the findings provided to her by the Government'' on a spreadsheet. Here again, there is no reference to this in the transcript, and even assuming that there was such a spreadsheet, the Expert fully explained the basis for her conclusions as to why the prescriptions she was asked about raised various red flags. These included that: (1) The patient's address was missing on some 169 prescriptions; (2) 98 prescriptions contained a stamped signature rather than the prescriber's actual signature; (3) the prescribers' DEA numbers were missing or incorrect on 33 prescriptions; (4) the name of the physician on the label was different from the name of the actual prescriber on 157 of the prescriptions; (5) several doctors were prescribing drug cocktails of narcotic and benzodiazepines; (6) a patient was prescribed a narcotic cough syrup in an amount that far exceeded the quantity ordinarily prescribed in the course of legitimate medical treatment; (7) some patients filled prescriptions for duplicative narcotics such as

[1] Respondent also contends that the ALJ overlooked the Expert's testimony that: she ''is only a fill-in part-time pharmacy at Walgreens and rarely works at the VA so she has no real applicable experience to assist the ALJ in understanding whether or not Respondent's errors were to such a degree as to support the decision that its continued registration is inconsistent with the public interest and should therefore be revoked.''

Exceptions, at 13. Respondent does not, however, cite to where in the transcript the quoted testimony occurred, and while the Expert acknowledged that she works as a relief pharmacist, at no point did she testify that ''she has no real applicable experience to assist the ALJ in understanding whether . . . Respondent errors were to such a degree as to support'' the ALJ's ultimate conclusion of law. I thus reject this contention.

hydrocodone tablets and hydrocodone cough syrup; (8) some patients only filled narcotic prescriptions and not their prescriptions for non-controlled drugs; (9) at least 22 times, Respondent returned the original prescription to a patient notwithstanding that it had filled the controlled substances and typically made no marking as to what it had filled on the returned prescription; (10) Respondent disregard physician's instructions to either fill all the prescriptions or none of them; (11) Respondent filled prescriptions in which the number of refills was left blank; and (12) and in five instances, the prescriptions had not been signed by the prescriber. R.D. at 10–12.

The Government's Expert further testified that it is the usual custom in pharmacy practice for a pharmacist to document his/her attempts to resolve red flags on the face of the prescription. Tr. 33. However, the Expert found no evidence that this occurred with respect to any of these prescriptions. *Id.*

In his sixth exception, Respondent contends that the ALJ's recommended sanction of revocation is arbitrary and capricious because it is ''unsupported by substantial evidence of egregious and intentional diversion.'' Resp. Exceptions, at 13–14. Putting aside for the moment whether this is so, Respondent correctly notes that this Agency considers the egregiousness and degree of culpability of a Registrant's misconduct in making the public interest determination. However, this Agency has long held that ''[j]ust because misconduct is unintentional, innocent, or devoid of improper motivation, [this] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial.'' *Paul J. Caragine, Jr.,* 63 FR 51592, 51601 (1998).

In any event, there is ample evidence of egregious misconduct including evidence that supports the inference that Respondent engaged in the intentional or knowing diversion of controlled substances. Here, the evidence shows that the Government conducted an audit of Respondent's handling of controlled substances which revealed massive shortages of multiple controlled substances. More specifically, the Government's audit, which covered slightly more than a one-year period, showed that Respondent had a shortage of 27,334 milliliters (929 ounces) of promethazine with codeine cough syrup (a schedule V drug); a shortage of 3,445 hydrocodone 10mg tablets (a schedule III drug), and shortages of 43,359 alprazolam 1mg and 7,769 alprazolam 2mg tablets (schedule IV).[2] Tr. 138–40; GX 13.

These shortages are extraordinary and support a finding of massive and egregious recordkeeping failures on Respondent's part. This alone supports a finding that Respondent violated the Controlled Substances Act, which requires the maintenance of ''complete and accurate'' inventories, as well as a ''complete and accurate record of each substance . . . received, sold, delivered or otherwise disposed of.'' 21 U.S.C. 827(a). And while later in his Exceptions, Respondent takes issue with the ALJ's findings regarding the audit, arguing that ''[t]he ALJ presumes these audit results are the correct and final tallies,'' Exceptions, at 24; notably, Respondent put forward no evidence that calls into question the validity of the audit's findings.

Moreover, the quantities involved support the inference that Respondent was engaged in the intentional diversion of controlled substances, given that it has put forward no evidence to provide a plausible explanation for the shortages.[3] And even if the Government proved no other violations, ''the audit results alone are sufficient to satisfy the Government's *prima facie* burden of establishing that Respondent's registration would be 'inconsistent with the public interest.''' *Fred Samimi,* 79 FR 18698, 18712 (2014) (quoting 21 U.S.C. 823(f)); *see also Medicine Shoppe-Jonesborough,* 73 FR 364, 386 (2008).

Nor is this the only evidence that supports a finding that Respondent engaged in intentional diversion. Rather, the Government showed that Respondent filled drug cocktails of narcotics such as hydrocodone, benzodiazepines such as alprazolam (Xanax), and Soma (carisoprodol).[4] Indeed, the Government's evidence showed that with respect to patient B.B., Respondent filled prescriptions she presented on a single day for 90 Norco (hydrocodone/apap) 10/325, 90 Xanax 1mg, 90 Soma 350mg, and four ounces of promethazine with codeine cough syrup.[5] GX 3, at 19–20. Moreover, the prescription B.B. presented did not include her address, a violation of 21 CFR 1306.05(a).[6] *Id.* at 19. B.B. was allowed to take the original prescription, notwithstanding that DEA's regulations require that the prescription be filed and maintained by the pharmacy. 21 CFR 1306.24(d). Finally, the evidence suggests that notwithstanding that B.B. had filled four of the five prescriptions on the form, no marking was made on the returned prescription to indicate that Respondent had dispensed the Norco, Xanax, Soma and promethazine with codeine prescriptions. *See* Tr. 53–54 (Expert's testimony that where Respondent returned the original prescription after dispensing controlled substances and did not mark through the drug or note the dispensing on the prescription, this ''allows the patient to refill the same two medications again at another pharmacy'').

There were also multiple other instances in which patients presented prescriptions for a similar drug cocktail of hydrocodone, alprazolam, and carisoprodol, and Respondent filled at least some of the prescriptions. *See* GX 3, at 43 (Rx for J.F., with no patient address, for 240 Norco 10mg, 60 Xanax 1mg, 120 Soma 350mg); *id.* at 47 (Rx to J.G., with no patient address, for 60 Vicodin Extra Strength, 60 Xanax 1mg, and 60 Soma); *id.* at 66–67 (Rx to K.J., with no patient address, for 90 Norco 10mg, 90 Xanax 1mg; 30 Soma; and 4 ounces of Tussionex (hydrocodone) cough syrup).; *id.* at 76 (Rx to S.J., with no patient address, for 240 Norco 10mg, 90 Xanax 1mg; 120 Soma 350mg, and 120 ml of phenergan with codeine); *id.* at 78 (Rx to B.M., with no patient address, for 60 hydrocodone 10/325mg, 60 alprazolam 1mg, 60 Soma 350mg, and 4 ounces of promethazine with codeine); *id.* at 90 (Rx to D.R., with no patient address, for 90 Vicodin 10/500, 60 Xanax 2mg, 60 Soma 350mg, and 4 ounces of Tussionex).

There were also other prescriptions which Respondent filled,

[2] The Government's evidence also showed that Respondent had overages of 445 tablets of methadone 10mg; 1,508 tablets of hydrocodone 5mg; and 18,721 of hydrocodone 7.5mg. Tr. 138–40; GX 13.

[3] Indeed, Respondent notes that the pharmacy has no ''history of break-ins or burglaries.'' Exceptions, at 15 (citing Tr. 157–58). Thus, theft is not a plausible explanation for the massive shortages.

[4] In decisions published before Respondent dispensed the prescriptions at issue here, DEA had discussed the abuse of drug cocktails which included hydrocodone, alprazolam, and carisoprodol. *See East Main Street Pharmacy,* 75 FR 66149, 66158 (2010) (testimony of expert in pharmacy that ''[i]t is well known in the pharmacy profession [that] the combination of a benzodiazepine, narcotic pain killer, and Soma [is] being used by patient abusing prescription drugs''); *Paul Volkman,* 73 FR 30630, 30637 (2008) (testimony of medical expert that ''prescrib[ing] drug cocktails . . . often including an opioid, . . . a benzodiazepine and Soma . . . greatly increased the chance for drug abuse, diversion, [and]/or addiction''). *See also George C. Aycock,* 74 FR 17529, 17531 n.4 (2009); *Your Druggist Pharmacy,* 73 FR 75774, 75775 n.1 (2008).

[5] The prescriptions were written on a single form, and also included a prescription for Lyrica which B.B. did not fill. GX 3, at 19–20.

[6] The labels for the dispensed prescriptions list B.B.'s address as being in Austin, Texas, which is some distance from San Antonio. GX 3, at 20.

notwithstanding that they provided for duplicative therapy of both hydrocodone tablets and narcotic cough syrups, such as Tussionex, which contains hydrocodone; Promethazine with codeine; and Cheratussin AC, a cough medicine which also contains codeine. Here again, the Expert noted that these prescriptions presented red flags which should have been resolved before dispensing the drugs because they contain ''the same ingredient or drug.'' Tr. 44–45. However, there was no evidence that Respondent's pharmacist even attempted to resolve the red flag. *Id.* at 45.[7] *See also* GX 3, at 13 (Tussionex and hydrocodone/apap 10/500); *id.* at 55 (Tussionex and Vicodin 10/500 along with Xanax); *id.* at 57 (Tussionex, Norco 10/325, and Xanax); *id.* at 60–65 (promethazine with codeine, Norco 10/325, and Xanax 2mg); *id.* at 70 (Tussionex, Norco 10/325, and Xanax); *id.* at 97 (Vicodin 10/500, Tussionex, and Xanax); *id.* at 104 (Norco 10/325, Promethazine with codeine, and Xanax 2mg); *id.* at 107 (Norco 10/325, Promethazine w/ codeine, and Xanax).

As it did with B.B., in several instances Respondent returned the original prescriptions to the patient and did so without making any markings or notes indicating that it had dispensed some of the controlled substances. *See* Tr. at 53–54. For example, M.F. presented prescriptions (all on the same form) which authorized the dispensing of both 90 alprazolam 1mg and 60 Xanax 1mg (these being the same drug) but with different dosing instructions, as well as 240 Norco 10mg. GX 3, at 41. While Respondent returned the original prescription to M.F., there is no indication on the copy it retained that it had noted on the original that it had dispensed the 90 tablets of alprazolam. *Id.* at 41–42. *See also id.* at 13 (no marking on Rx indicating dispensing of hydrocodone and alprazolam); *id.* at 43 (no marking on Rx indicating dispensing of alprazolam); *id.* at 70 (no marking on RX indicating dispensing of Tussionex); *id.* at 90 (no marking on Rx indicating dispensing of Xanax); *id.* at 104 (no marking on Rx indicating dispensing of alprazolam and promethazine w/codeine).[8]

In still another other instance, Respondent dispensed a prescription for a 30-day supply of promethazine with codeine cough syrup. GX 4, at 218–19. According to the Expert, cough syrups are typically dispensed in 10–14 day quantities ''for the length of the cough.'' Tr. 47. Moreover, here again, the prescription did not contain the patient's address and was facially invalid. *Id.* at 47; GX 4, at 218. Yet there was no evidence that Respondent resolved the red flags raised by the prescription. Tr. 47; GX 4, at 218–19.[9]

Accordingly, I reject Respondent's assertion that it's ''misconduct cannot be characterized as anything more than negligence.'' Exceptions, at 15. Between the shortages of tens of thousands of dosage units of controlled substances and the numerous dispensing violations, many of which establish that Respondent's pharmacists were engaged in knowing or intentional diversion, the Government has more than met is burden in showing why Respondent's misconduct is egregiousness enough to warrant revocation.[10]

Respondent further argues that because it was not subject to an immediate suspension of its registration and has been permitted to continue to operate since the execution of the Administrative Inspection Warrant in October 2011, ''[t]hese factors militate against revocation.'' *Id.* They don't. The decision as to whether to commence a proceeding by simply issuing an Order to Show Cause or by issuing an Immediate Suspension Order is fully within the Government's prosecutorial discretion, subject of course, to the requirement applicable to the latter that a finding be made that a registrant's continued registration poses ''an imminent danger to the public health or safety.'' 21 U.S.C. 824(d). Indeed, as the Supreme Court has made clear, ''except for [in] extraordinary situations where some valid governmental interest is at stake that justified postponing the hearing until after the'' initial deprivation, the Due Process Clause requires pre-deprivation process when the Government seeks to terminate a property interest. *Boddie* v. *Connecticut,* 401 U.S. 371, 379 (1971). Beyond this, in an ordinary Show Cause Proceeding, the Government is not required to prove that a registrant poses ''an imminent danger to the public health or safety,'' but rather, only whether the registrant ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). This standard has clearly been met here.[11]

[7] The Expert also explained that ''hydrocodone is a codeine derivative.'' Tr. 44.

[8] In another instance in which Respondent return the hard copy of a prescription to B.M., there are check marks next to hydrocodone, alprazolam, and promethazine, each of which was dispensed on the date the prescription was issued. GX 3, at 78. As the original prescription is not in the record, it is unknown whether these checkmarks were placed on it. However, none of the three drugs were lined out and there is no other notation advising any subsequent pharmacist to whom B.M. might present the prescription that the drugs had been dispensed by Respondent. *Id.*

[9] The prescription also authorized one refill. While there is no evidence that Respondent refilled the prescription (as there is no label corresponding to a refill on the back of the copy of the prescription), as noted above, Respondent had a shortage of more than 27,000 milliliters of promethazine with codeine.

[10] So too, I reject Respondent's eighth exception, in which it argues that most of the suspicious prescriptions raised resolvable red flags and ''unresolvable red flags were not the type that predominated with the Respondent.'' Exceptions, at 18. Notably, as the Government's Expert testified, while some of the red flags were resolvable, there was no evidence that Respondent's pharmacists ever attempted to do so. *See generally* Tr. 30–69, 75, 82–83, 85. As for its contention that prescriptions which raised ''unresolvable red flags'' did not ''predominate[]'' at Respondent, suffice it to say that there were more than enough of them to conclude that Respondent knowingly diverted controlled substances.

In this exception, Respondent also contends that even the Government's Expert acknowledged that sometimes patients may have been given drug samples and thus may not need to fill all of their prescriptions at that time, as well as that some lower income ''patients do not have the funds to get both non-controlled and controlled substances filled at the same time.'' Exceptions, at 18. Putting aside that most of the controlled substances at issue here are available as generic drugs, the fact that a patient may not have sufficient funds to fill all of his/her prescriptions does not excuse Respondent's practice of returning the original prescription form to the patient and then failing to mark on the form what drugs have been dispensed, thus allowing the patient to present the prescription to another pharmacy for filling.

[11] In his seventh exception, Respondent contends that the ALJ's analysis was arbitrary and capricious because she failed to consider factor one—the recommendation of the state licensing board—and factor three—the registrant's conviction record of controlled substances offense. Exceptions, at 16. It is true that the ALJ made no findings with respect to either factor. *See* R.D. at 21–31.

For purposes of this review, I have assumed that Respondent holds an unrestricted state license. There is, however, no recommendation from the Texas State Board of Pharmacy in the record. Moreover, even assuming that Respondent retains its state license (and that its license is not subject to any restrictions on its controlled substance dispensing authority), DEA has repeatedly held that while a practitioner's possession of state authority constitutes an essential condition for 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,* 472 Fed. Appx. 453, 455 (9th Cir. 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie,* 68 FR 15227, 15230 (2003). As the Agency has long held, ''the 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 Respondent satisfies the CSA's requirement that it be currently authorized to dispense controlled substances under the laws of the State in which it practices pharmacy, this factor is not dispositive either for, or against, the continuation of Respondent's registration. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As for factor three, I find that there is no evidence that either Respondent, or its principal, has been

Continued

Exceptions Two and Three—The ALJ's Failure To Rule on the Government's Motion *in Limine* and Rejection of Respondent's Testimony Regarding Remedial Measures

According to Respondent, in its Prehearing Statement and Supplemental Prehearing Statement, it provided notice of its intent to introduce evidence of its remedial measures. Exceptions, at 5–6. In response, the Government filed a Motion *in Limine* to bar the evidence on the ground that because Respondent had provided no notice of its intent to accept responsibility for its misconduct, this evidence was irrelevant. *Id.* at 6. Thereafter, Respondent filed a ''Motion for Leave to File Second Supplemental Prehearing Statement,'' which included a section in which Respondent provided notice to the Government ''admit[ting] that the Government . . . has met its burden and shown by a preponderance of evidence that Respondent has committed acts inconsistent with the public interest.'' Response to Gov. Motion *in Limine* and Motion for Leave to File Resp.'s Second Supp. Pre-hearing Statement, at 2.[12]

According to Respondent, ''the ALJ never ruled on the Government's Motion *in Limine* and never gave [it, *i.e.,* Respondent] permission to include in its Prehearing Exhibits any evidence related to the remedial measures it had taken since being served with the'' Administrative Inspection Warrant. Exceptions, at 6. Respondent maintains that had such permission been granted, it would have put forward such evidence as its policies and procedures, continuing education certificates, evidence of criminal background checks conducted on its employees, and its operations manual which includes training of its pharmacists and pharmacy technicians in identifying and resolving red flags. *Id.* at 6–7. However, it then asserts that because the ALJ ''had not granted [it] permission to supplement its [p]rehearing [e]xhibits . . . it was consigned to discussing these remedial measure through the sworn testimony of'' its owner. *Id.* Continuing, Respondent asserts that because the ALJ ultimately gave little weight to its owner's testimony, the ALJ ''put Respondent in an unwinnable situation.'' *Id.* at 9.

While it is true that the ALJ did not rule on either the Government's motion *in limine* or Respondent's motion to file a second supplemental pre-hearing statement prior to the hearing, I find Respondent's argument entirely unpersuasive for several reasons. First, Respondent ignores that prior to the ALJ's ruling, it filed a Response to the Government's Motion *in Limine* in which it expressly stated that it ''does not intend to introduce any other documentary evidence other than that made a part of his'' Supplemental Pre-Hearing Statement. Response to Gov't Mot. in Limine, at 5. However, in its Supplemental Pre-Hearing Statement, Respondent had proposed to introduce only three exhibits: (1) A criminal background check of its employee A.G. from 2008; (2) a copy of the Texas Board of Pharmacy rule establishing disciplinary sanctions on licensees and registrants for various criminal offenses (22 Tex. Admin. Code § 281.64); and 3) prescription copies (front and back) for nine patients. Resp. Supplemental Pre-Hrng. Statement, at 23. While Respondent did introduce both the criminal background check on A.G. and the Board of Pharmacy rule, neither of these was probative of the issue of whether Respondent has undertaken sufficient remedial measures to rebut the Government's *prima facie* case.

Second, while the ALJ did not rule on either motion prior to the hearing, her Order made clear that she would ''decide on the admissibility of each piece of evidence as it is offered.'' Order Deferring Judgment on Govt. Mot. *in Limine* and Resp.'s Mot. to File Second Supp. Prehearing Statement, at 2. However, at the hearing, Respondent did not seek to introduce any documentary evidence other than the two exhibits identified above.

Third, notwithstanding that in its Pre-Hearing Statement, Respondent identified two witnesses (A.C., a pharmacist, and R.G., a pharmacy tech) in addition to its owner/pharmacist-in-charge, and proffered that these witnesses would testify as to various procedures being employed by the pharmacy to ensure compliance with federal law, *see* Resp. Pre-Hrng. Statement at 19–21, Respondent did not call either person to testify. Notably, in its Response to the Government's Motion *in Limine,* Respondent continued to identify these two witnesses (in addition to its owner) as offering ''testimony [that] is relevant and material to show the Respondent will not engage in future misconduct.'' Resp. to Govt's Motion *in Limine,* at 5. Thus, even if the ALJ's deferral of her ruling created some uncertainty as to whether the testimony of these witnesses would be admissible, Respondent's failure to call these witnesses constitutes a waiver of the issue.

Nor do I find merit in Respondent's contention that the ALJ imposed on it an undefined and vague standard of proof when she rejected its owner's testimony as to several assertions regarding remedial measures it had undertaken in the absence of corroborating evidence. Indeed, even were I to find some merit to this contention, it would not change my ultimate decision, because Respondent ignores that the ALJ also questioned the credibility of its owner's testimony regarding his acceptance of responsibility. Moreover, my own review of the record finds that Respondent's testimony as to his acceptance of responsibility is properly described as double talk, because while he initially testified that he accepted responsibility for his misconduct, on further questioning he denied having ever diverted drugs. So too, while the Government put forward Expert testimony that there were numerous prescriptions which raised red flags and which should not have been filled, either because Respondent never attempted to resolve the red flag (if it was resolvable) or the red flags were not resolvable, Mr. Lewka nonetheless maintained that there were no prescriptions which Respondent should not have filled.

While the ALJ noted that on direct examination, Mr. Lewka took full responsibility for its misconduct, she further found that on cross-examination, ''he presented testimony inconsistent with other testimony in the record.'' R.D. at 29. As support, the ALJ specifically noted Mr. Lewka's testimony regarding the hiring of A.G. to work as a driver delivering prescriptions, including controlled substance prescriptions. *Id.; see also* Tr. 127. As explained above, this was a violation of DEA regulations. *See* 21 CFR 1301.76(a). According to A.G., he told Mr. Lewka that he had a felony conviction for distributing controlled substances before he started working for Respondent. Tr. 16. Mr. Lewka denied

convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. There are, however, a number of reasons why a person (whether a corporate entity or natural person) may never be convicted of an offense falling under this factor, let alone be prosecuted for one. Thus, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is not dispositive. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay v. DEA,* 664 F.3d 808 (10th Cir. 2011).

I therefore reject Respondent's exception.

[12] In this pleading, Respondent provided notice that it intended to withdraw two witnesses it had previously identified as J.A.C. and L.D.A. Resp. to Gov. Mot. *in Limine* and Motion for Leave to File Resp.'s Second Supp. Prehearing Statement, at 5. However, Respondent reiterated its earlier notice that it intended to call Respondent's owner and pharmacist-in-charge, a second pharmacist-employee, and a pharmacy technicians, maintaining that ''their testimony is relevant and material to show the Respondent will not engage in future misconduct.'' *Id.*

this, *id.* at 200–01, even though the evidence showed that Lewka told A.G. to obtain his criminal history and A.G. obtained a letter from the San Antonio, Texas Police Department, which while showing that he had not been arrested by San Antonio police, explicitly stated that the ''background check does not include [the] Bexar county Sheriff['s] Office, other cities, counties or states.'' RX 1.[13]

Moreover, a DEA Investigator credibly testified that she had told Mr. Lewka that A.G. had a felony conviction in July of 2013. R.D. at 14 (citing Tr. 132). Mr. Lewka continued to employ A.G. until September 2013, Tr. 14, maintaining that DEA did not tell him that A.G. was a convicted felon until September 2013. *Id.* at 204; *see also* R.D. at 29.

As another example of his inconsistent testimony regarding his acceptance of responsibility, the ALJ relied on Mr. Lewka's testimony regarding Respondent's handling of various prescriptions, which contained prescriptions for both controlled and non-controlled drugs and which were stamped by the physician's instruction to the pharmacy to fill ''all or none'' of the prescriptions. The Government produced evidence showing that in several instances, Respondent had dispensed only the controlled substances and/or disregarded the physician's instruction to fill ''all or none.'' *See* GX 3, at 15, 17, 55, and 96.

As for Mr. Lewka's testimony regarding this conduct, the ALJ found that he ''seemed to deny that there was any misconduct when the prescription contained both controlled substances and non-controlled substances,'' or included the physician's instruction to fill ''all or none'' of the prescriptions'' and ''was filled by only distributing the controlled substances.'' R.D. at 29. As the record shows, the Government specifically asked Mr. Lewka regarding a prescription for three drugs, including promethazine with codeine cough syrup, issued to patient L.B. which was stamped in two places with the instruction ''ALL OR NONE.'' Tr. 206; GX 3, at 15. The evidence further showed that Respondent dispensed only the promethazine with codeine. *See* GX 3, at 16.

When asked if he had disobeyed the prescribing physician's instructions, Mr. Lewka asserted: ''[t]hat's not true'' because he had personally called the physician. Tr. 206. When then asked why there was no such note on the prescription,[14] Mr. Lewka asserted that the note was ''on the computer'' and that one of the Agency's Investigators ''was supposed to access what we have in the computer that attached to most of these prescriptions.'' *Id.* at 207. However, when the Government pointed out that the Show Cause Order had specifically alleged that Respondent's dispensing of this prescription was unlawful, Mr. Lewka asserted that he didn't know that he would have to bring his computer notes. *Id.* at 207–08.

When the Government again asked Mr. Lewka whether he was accepting responsibility, he asserted that he was ''accepting responsibility, but . . . was explaining what I did on the process.'' *Id.* at 210. However, when the Government again asked whether he had disobeyed the doctor's ''all or none'' instruction, Mr. Lewka again asserted that he had talked to L.B.'s doctor. As for what L.B.'s doctor told him, Mr. Lewka replied:

> Well, he said one of the problems he having [sic] is he put them in to see if they'll get them, but if they don't have insurance, than they should get what they want. I told him personally, I said, [q]uit having your employee stamp the prescriptions; it's affecting the customers. He said, [t]hat's the procedure we do here, and they're supposed to fill the prescriptions at that doctor's pharmacy, and I don't know why they brought them out. That's what he told me. And he make me have some of them come back with the prescriptions.

Tr. 210.

Noting that Respondent failed to produce any evidence to support Mr. Lewka's claim that he had called the physician who approved his filling only the promethazine, the ALJ concluded that ''[t]his inconsistent testimony certainly calls into question [his] genuine remorse for the misconduct proved by the Government.'' R.D. at 29. Indeed, on this issue, Mr. Lewka testified out of both sides of his mouth, and as ultimate factfinder, *see* 5 U.S.C. § 557(b), I do not believe his testimony that a physician who had previously instructed the pharmacist to fill ''all or none'' of a prescription, would then tell the pharmacist that the patient ''should get what they want.''

Moreover, while Mr. Lewka offered a generalized acceptance of responsibility to the allegations, other portions of his testimony demonstrate that he is not sincerely remorseful. When asked by his counsel to explain his professed understanding of ''the importance of avoiding diversion'' and why this Agency is concerned with diversion, Mr. Lewka testified:

> Well, that the cocktail medication that you fill in the pharmacy has to be for good legitimate reasons, and diversion is costing the country and everybody a lot of problems. There's a lot of drug addicts out there, *but I never do diversion at Medicine Shoppe.* I never knew that some of the things they said on the paper was diversion. I looked at it. It's not diversion at that point, because I've already talked to the doctor. I know the patient, and I also do what they want us to do now, making sure that you are also liable for what the patient is doing.
>
> But diversion is when multiple patients . . . bring cocktail medication, like controlled substances, Xanax, Soma, hydrocodone, all in one prescription, scripts, with the intent to—like in this case, if Dr. [L] give me a prescription with all the same patients have the same prescriptions, and they brought it to the pharmacy, and we were filling it, we made a lot of calls to him, especially those that work for him, all they say, That's what the doctor wants, and that's how the doctor write his prescriptions.

Tr. 197 (emphasis added). Unexplained by Mr. Lewka is why, if he never does

[13] In his ninth exception, Respondent challenges the ALJ's finding that it violated DEA regulations because it employed a person with a felony drug conviction as its delivery driver. Exceptions, at 19–23. While Respondent does not dispute that this was a violation of a DEA regulation, it argues that the ALJ acted arbitrarily and capriciously because she ''placed great emphasis'' on the violation, which it maintains was unintentional. *Id.* at 19–20. It further maintains that the former employee ''lied during his testimony and stated that he informed [Respondent's owner] at the time he was hired as a delivery driver in 2008 that he had a felony conviction for a drug offense.'' *Id.* at 20.

To the extent the ALJ found credible the former employee's testimony that he had told Respondent's owner about his felony drug conviction at the time of his employment interview, *see* R.D. at 29, I adopt her finding. Indeed, the evidence showed that following the interview, Respondent directed the employee to obtain his criminal history. Thus, there was obviously some discussion between the employee and Respondent's owner as to the former's criminal history.

Most significantly, the report which was provided by the San Antonio Police Department clearly indicated that it was limited to the Police Department's records and did not include the records of the ''Bexar County Sheriff,'' as well as others cities, counties or states. RX 1. Given this disclaimer, Respondent cannot credibly claim that he was duped when the report came back negative for any criminal history. *See* Exceptions at 21 (asserting that Respondent's owner ''was duped and did not know that the Bexar County Sheriff's Department criminal records check would not contain all of A.G.'s criminal history''). Moreover, as the employer, Respondent's owner was the person responsible for conducting a proper background check. Thus, even if his failure to perform a proper background check does not rise to the level of an intentional violation of the regulation, it was still properly considered by the ALJ as evidence of his compliance with applicable laws related to controlled substances. *See* 21 U.S.C. § 823(f)(4). Notably, the ALJ did not state that this violation alone was sufficient to warrant the revocation of Respondent's registration. Nor do I. I thus reject this exception.

[14] The Government's Expert testified that a red flag is raised when a customer presents a prescription for both controlled and non-controlled drugs but requests that the pharmacy fill only the controlled substances. Tr. 32–33. She further testified that the resolution of the red flag would be documented ''directly on the hard copy prescription and possibly in the patient's profile.'' *Id.* at 33.

diversion, he even offered his token acceptance of responsibility. So too, in Mr. Lewka's view, only when drug cocktails of Xanax, Soma (carisoprodol) and hydrocodone are prescribed to multiple patients are the prescriptions being diverted; thus, if a single patient presents these prescriptions, it is not diversion and is appropriate to fill the prescriptions. And as long as the doctor's staff says that a cocktail of these three drugs is ''what the doctor wants, and that's how the doctor write his prescriptions,'' it is appropriate to fill the prescriptions.

This view, however, has been squarely rejected by both the federal courts and this Agency. *See United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979) (''Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification.''); *United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980) (upholding jury instruction that knowledge may be inferred from evidence that pharmacists ''deliberately close their eyes to what would otherwise be obvious to them''); *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62315, 62322 n.26 (2012) (noting that ''for more than thirty years (if not longer), it has been settled law that a pharmacist can be held liable for violating 21 CFR 1306.04(a) even if he calls the prescriber and verifies the prescriptions''); *Ralph J. Bertolino,* 55 FR 4730 (1990).

Moreover, when asked whether there were ''any specific prescriptions'' which the Government's Expert opined should not have been filled, which he ''agree[d] should not have been filled,'' Tr. 219, Respondent again offered testimony inconsistent with his earlier statement that he accepted responsibility. He testified that:

> There's *no prescription* that she said that I shouldn't have filled that I looked at it from her point of view. But most of the things she said was factual. But not filling the prescriptions—I know the prescription; I know the doctors; I know the patients more than she does, so she was looking at it from somebody who do relief. I don't relieve. I'm a regular pharmacist on this station, so I know most of my customers.

Tr. 219–20 (emphasis added).

However, as explained above, the Expert identified twelve different issues with the prescriptions Respondent filled. These include, *inter alia,* that various prescriptions were missing the patient's address; some prescriptions bore a stamped signature rather than the prescriber's actual signature; some prescriptions were entirely missing the prescriber's signature; some prescriptions were missing the prescriber's DEA number; some labels bore a different prescriber name than that of the actual prescriber; some doctors were prescribing drug cocktails of narcotics, benzodiazepines, and carisoprodol; some patients were filling prescriptions for duplicative narcotics such as hydrocodone tablets and hydrocodone cough syrups; and a prescription for a narcotic cough syrup authorized the dispensing of a quantity of the drug that far exceeded the quantity ordinarily prescribed in the course of legitimate medical treatment. Finally, Respondent filled controlled substance prescriptions for multiple patients and then returned the original prescriptions to the patients without making any marking on the original prescriptions that a controlled substance had been dispensed, thus allowing the patients to obtain the same drug at a second pharmacy.[15]

Yet Respondent asserted that none of these dispensings was improper. Moreover, as the ALJ found, Respondent entirely failed to address the shortages found during the DEA audit.

I thus conclude that Respondent has not accepted responsibility for its misconduct. As such there is no need to address whether the remedial measures he claims to have instituted are adequate to protect the public interest. *Medicine Shoppe—Jonesborough,* 73 FR 363, 387 (2008). Indeed, in light of Mr. Lewka's testimony to the effect that it is appropriate to fill prescriptions for drug cocktails as long as the doctor's staff tells him that is how the doctor writes his prescriptions, I would still conclude—even were I to give weight to all of Mr. Lewka's testimony as to his remedial measures—that his understanding of his obligations as a dispenser of controlled substances is so lacking as to preclude a finding that Respondent's registration is consistent with the public interest. *See* 21 U.S.C. 823(f) and 824(a)(4).

Finally, in its twelfth exception, Respondent contends that the ALJ's recommended order of revocation is arbitrary and capricious because:

> [c]urrent DEA precedent sets up a no win scenario for any registrant that has in its history one or two violations of DEA Regulations. That is, DEA precedent holds that unless the Respondent accepted responsibility for its ''misconduct.'' Even if there is no intentional diversion by the Respondent. Consequently, the Respondent's due process rights have been denied since there is no meaningful and fair due process proceeding available.

Exceptions, at 25–26.

As found above, Respondent is in no position to argue that it has been placed in a ''no win'' scenario either because it has committed only one or two violations of DEA regulations or has not intentionally diverted controlled substances. Rather, the record is replete with various violations of the CSA, including violations which support a finding that it intentionally diverted drugs. So too, the record establishes that it cannot account for tens of thousands of dosage units. Thus, to the extent Respondent is in a ''no win scenario,'' this is entirely of its own making.

As for its opaque suggestion that it has been denied a fair hearing because the Agency's precedent required it to acknowledge its misconduct, this is an argument which, while not framed in constitutional terms, has previously been tried and rejected. As the Tenth

[15] In his tenth exception, Respondent maintains that his recordkeeping deficiencies ''were situational and the result of the turbulent and catastrophic demise and ultimate death of Mr. Lewka's wife.'' Exceptions, at 23. The record is, however, devoid of any evidence to support this contention.

Respondent also argues that his recordkeeping errors are not sufficiently egregious to warrant revocation. *Id.* (citing *Terese, Inc., d/b/a Peach Orchard Drugs,* 76 FR 46483, 46848 (2011)). Respondent also cites *Howard N. Robinson,* 79 FR 19356 (2014) (in his eleventh exception), apparently arguing that the audit results should be considered along with the evidence as to their underlying cause.

As for the first contention, in *Terese,* the Government put forward no evidence that it had done an audit and found that the pharmacy could not account for the controlled substances it handled, and the three recordkeeping violations that were proved were comparatively minor and corrected as soon as they were brought to the attention of the pharmacist. *See* 76 FR at 46848. So too, while in *Robinson,* the Administrator rejected the Government's contention that the audit results warranted the revocation of his registration, she noted that the ALJ had found that the physician had put forward credible evidence that the shortages were the result of diversion which was committed by ''a rogue employee, who happened to be a convicted drug smuggler,'' who was hired by the physician's employer and not the physician, and had since been terminated. 79 FR at 19357. Moreover, the Administrator noted that the physician's misconduct was merely negligent, that he ''fully accepted responsibility and demonstrated that he [wa]s not likely to commit similar omissions in the future.'' *Id.* By contrast, in this matter, Respondent has failed to offer any explanation as to the likely cause of the massive shortages found during the audit, and while Respondent contends that the ALJ ignored evidence that Mr. Lewka had hired an independent company to conduct an inventory, Exceptions, at 24; an inventory and audit are not the same, and in any event, there is no evidence in the record establishing that Respondent hired an independent firm to conduct either inventories or audits.

Circuit held in rejecting a challenge to the Agency's rule:

> The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the Deputy Administrator to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether continued registration is in the public interest.

MacKay v. *DEA,* 664 F.3d 808, 820 (10th Cir. 2011) (citing *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005)); *see also Hoxie,* 419 F.3d at 483 (''The DEA properly considers the candor of the physician . . . and admitting fault [to be] important factors in determining whether the physician's registration should be revoked.''). I therefore also reject this exception.

Conclusion

Finding no merit in any of Respondent's Exceptions, I reject its contention that I should either reopen the hearing or impose a lesser sanction such as probation with monitoring. Because I find that substantial evidence supports the conclusion that Respondent's registration is ''inconsistent with the public interest,'' 21 U.S.C. 824(a)(4), I adopt the ALJ's recommendation that I revoke its registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration BT8599891, issued to The Medicine Shoppe, be, and it hereby is, revoked. I further order that any pending application of The Medicine Shoppe to renew or modify its registration be, and it hereby is, denied. This Order is effective November 3, 2014.

Dated: September 18, 2014.

Thomas M. Harrigan,

Deputy Administrator.

Frank Mann, Esq., for the Government.
Jeffrey C. Grass, Esq., for the Respondent.

RECOMMENDED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

I. INTRODUCTION

Gail A. Randall, Administrative Law Judge. This proceeding is an adjudication governed by the Administrative Procedure Act, 5 U.S.C. §§ 551 *et. seq.,* to determine whether a pharmacy's registration with the Drug Enforcement Administration (''DEA'') should be revoked and any pending applications for renewal of such registration be denied under the Controlled Substances Act, 21 U.S.C. §§ 823(f) and 824(a).

I. PROCEDURAL BACKGROUND

On October 7, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause, proposing to revoke DEA Certificate of Registration, Number BT8599891, of the Medicine Shoppe, (''Respondent''), as a retail pharmacy, pursuant to 21 U.S.C. § 824(a), and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C.§ 823(f). [Administrative Law Judge Exhibit (''ALJ Exh.'') 1]. On October 18, 2013, The Medicine Shoppe, through counsel, filed a written request for a hearing. [ALJ Exh. 2].

A hearing was held in San Antonio, Texas, on January 7, 2014. [ALJ Exh. 4]. On February 18, 2014, the Government filed its Proposed Findings of Fact and Conclusions of Law (''Government's Brief''). Also on February 18, 2014, the Respondent filed its Proposed Findings of Fact and Conclusions of Law (''Respondent's Brief'').

II. ISSUE

The issue in this proceeding is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration should revoke the DEA Certificate of Registration, Number BT8599891, of The Medicine Shoppe, as a retail pharmacy pursuant to 21 USC § 824(a), and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f), because its continued registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). [ALJ Exh. 3; Transcript ''Tr.'' at 5].

III. FINDINGS OF FACT

I find, by a preponderance of the evidence, the following facts:

A. Stipulated Facts

The parties have stipulated to the following fact: Respondent is registered with DEA as a retail pharmacy authorized to handle controlled substances in Schedules II–V under DEA COR (Certificate of Registration) number BT8599891 at 2004 East Houston Street, San Antonio, Texas. DEA Certificate of Registration BT8599891 will expire by its terms on November 30, 2015. [ALJ Exh. 3; Tr. at 7–8].

At the hearing, the parties also stipulated to the following fact: Respondent, The Medicine Shoppe, employed and paid wages to A.G. during the years 2011, 2012, and 2013. [Tr. at 8].

B. The Investigation

Diversion Investigator (''DI'') Ramirez has been a Diversion Investigator for DEA for approximately four-and-one-half years. [Tr. 102]. She began her investigation of the Respondent after she learned that patients of a specific doctor accused of issuing illegitimate prescriptions were filling those prescriptions at the Respondent pharmacy. [Tr. 103]. The investigation was not started in response to any complaints about the Respondent's dispensing practices. [Tr. 157].

On November 9, 2011, an administrative inspection warrant was executed at the Respondent's location. [Tr. 159]. DEA inspected and copied Respondent's records, to include original prescriptions, copies of prescriptions, records showing the receipt of controlled substances, and computer data [16]. [Tr. 108]. From that date until the present, the pharmacy continued to operate. [Tr. 161]. The record shows that Mr. Lekwa, owner and pharmacist in charge, was cooperative with the DEA. [Tr. 164].

The record contains no evidence that the Respondent pharmacy, any pharmacist or pharmacy technician who has worked for the Respondent has ever been charged with any crime by a state or federal law enforcement agency.[17] [Tr. 183]. Further, the Respondent has not had any suspicious reports regarding break-ins or burglaries. [Tr. 157–58].

C. Red Flags

Dr. Amy Poore Witte works at the University of the Incarnate Word, San Antonio, Texas. Since July of 2006, Dr. Witte has served as an associate professor with tenured status in the Department of Pharmacy Practice. [Tr. 26–27]. In May of 2004, Dr. Witte was awarded her doctorate of pharmacy degree. [Tr. 27–28]. Dr. Witte worked as a licensed pharmacist for Walgreens from 2004 to 2010, and she currently has a clinical pharmacist position at the VA Hospital in San Antonio, Texas. [Tr. 28]. As a licensed pharmacist, Dr. Witte has experience in dispensing controlled substances. [Tr. 29; Government Exhibit (''Gov't Exh.'') 2].

As a professor, Dr. Witte taught a class in pharmacy law, and she is familiar with the requirements for dispensing controlled substances under both Texas and federal law. [Tr. 29–30]. Dr. Witte was the Government's witness and was recognized as an expert witness in the field of retail pharmacy. [Tr. 35].

Dr. Witte explained the method a pharmacist would use to dispense a controlled substance. First, the pharmacist would look at the prescription to determine if it is facially valid. Specifically, the pharmacist would ensure the prescription contains the patient's name and address. Next, she would look at the bottom of the prescription to verify that a physician has manually signed the prescription, and has entered the date of the prescription and a DEA number. Lastly, she would look at the body of the prescription for the drug name, the strength or dose of the drug, the quantity to dispense, and the directions for use. [Tr. 30].

Dr. Witte confirmed that a pharmacist has a corresponding responsibility to ensure that a prescription for a controlled substance is issued for a legitimate medical purpose. [Tr. 31]. To determine this purpose, the

[16] DEA had difficulties downloading data from the Respondent's computer. DI Ramirez testified that this was why information from the computer was not utilized or made part of the record in this proceeding. [Tr. 166].

[17] However, the Respondent hired and fired a delivery driver with a felony conviction related to the handling of controlled substances. This will be discussed *infra.*

pharmacist talks to the patient and reviews the patient's prescription profile. [Tr. 31]. The pharmacist looks to determine if the patient has used the controlled substance in the past, whether the patient is obtaining the drug from multiple physicians, and whether the prescription is tailored to the patient's needs. [Tr. 31–32].

The pharmacist may encounter ''red flags'' when presented with the prescription. Dr. Witte defined a ''red flag'' as something ''brought to your attention when looking at the prescription which could lead you to think there may be signs of drug diversion.'' [Tr. 32]. Examples of ''red flags'' would be a prescription for an unusually large quantity of the controlled substance, irregular dosing instructions, and a patient opting to fill only controlled substances on a prescription that also contains a noncontrolled substance. [Tr. 32–33]. It is accepted practice for a pharmacist to investigate the ''red flag'' and to note on the hard copy of the prescription the results of that investigation. [Tr. 33]. Such investigation takes place before the drug is dispensed. [Tr. 33].

Dr. Witte reviewed several hundred prescriptions dispensed at the Respondent. [Tr. 36; Govt Exhs. 3, 4, 8, 9]. These prescriptions were for both controlled and noncontrolled substances. [Tr. 36]. In general, Dr. Witte noticed that there were issues with the prescriptions, to include 1) missing patients' addresses, 2) missing DEA numbers, 3) the wrong physician's name on the dispensing label, 4) stamped signatures instead of manual signatures, and 5) prescribing patterns by specific physicians. [Tr. 37]. It is not acceptable pharmacy practice to dispense a prescription without an address, with a stamped signature, or with a missing DEA number. [Tr. 37–38].

Dr. Witte also explained that a ''drug cocktail'' is usually two or more controlled substances on a prescription that are usually highly abused drugs sought by drug-seeking individuals. [Tr. 39]. A prescription containing a ''drug cocktail'' would be a potential ''red flag'' for diversion. [Tr. 39]. In one instance, customer C.H. received a ''drug cocktail'' of Tussionex, hydrocodone, and alprazolam. The prescription also contained non-controlled substances, which the customer declined to get filled. The non-controlled substances were ''maintenance meds'' which are ''used to treat chronic health conditions'' and would be needed ''right away.'' [Tr. 60; Gov't Exh. 3 at 57–58]. Dr. Witte noted that the resolution of this ''red flag'' was not annotated on the prescription, and accordingly, these prescriptions should not have been filled.

''Pattern prescribing'' occurs when a physician prescribes the same drug and the same dosage to every patient the physician sees. This is another ''red flag,'' for the prescription should be tailored to each patient's individual needs based on their chronic conditions. [Tr. 39–40]. In reviewing prescriptions from the Respondent, Dr. Witte recalled seeing prescriptions that were indicative of pattern prescribing by a Dr. Edwards. [Tr. 40]. Prior to September of 2011, Dr. Edwards prescribed Xanax and hydrocodone to all of his patients [18]. [Tr. 40]. Dr. Witte reviewed a specific prescription of Dr. Edwards' that fit this pattern. [Tr. 41; Gov't Exh. 9 at 66]. She also noted that the prescription contained a stamped signature. [Tr. 41; Gov't Exh. 9 at 66]. The dosing instructions were also unusual. All of these examples would be ''red flags'' for potential diversion. [Tr. 42; *see also* Gov't Exh. 9 at 68]. The prescription contains no evidence that these ''red flags'' were investigated prior to the dispensing of these drugs. [Tr. 42]. In Dr. Witte's opinion, these drugs should not have been dispensed without resolving these ''red flags.'' [Tr. 42].

Another of Dr. Edwards' prescriptions contained two drugs that were codeine based. [Gov't Exh. 8 at 7]. Dr. Witte explained that such prescribing would be a ''red flag'' and she would not have dispensed this prescription without first talking to the physician to suggest he change one of the codeine derivative drugs. [Tr. 44–45]. The prescription did not contain any evidence that this ''red flag'' was resolved prior to dispensing the drugs. [Tr. 45].

Dr. Edwards also prescribed two medications to patient D.K., hydrocodone, a Schedule III controlled substance, and Skelaxin, a non-controlled drug. Both of these drugs are designed to treat the same condition in the same manner. [Tr. 45–46; Gov't Exh. 8 at 16]. Dr. Witte found that this would be a ''red flag,'' and the prescription fails to contain an annotation of the actions taken to resolve this ''red flag'' prior to dispensing the drugs. [Tr. 46].

Reviewing another prescription, Dr. Witte noticed that a cough syrup containing codeine, promethazine with codeine, was dispensed in a thirty-day amount. [Tr. 47; Gov't Exh. 4 at 218]. Dr. Witte explained that cough syrup is usually not dispensed in such an amount. Rather, a cough syrup is dispensed for the length of the illness, usually ten to fourteen days. [Tr. 47]. Also, the address is missing on this prescription. [Tr. 47; Gov't Exh. 4 at 218]. These would be two ''red flags'' for this prescription. The prescription contains no evidence that these ''red flags'' were resolved prior to dispensing the medication. [Tr. 47–48].

Reviewing another prescription, Dr. Witte noted that a prescription was presented with the refill portion of the prescription left blank. [Tr. 48; Gov't Exh. 4 at 98]. That would be a ''red flag,'' for the prescription was for a controlled substance, and anyone could have filled in the refill number prior to presenting the prescription for dispensing. [Tr. 48]. The second prescription on the page was for a controlled substance and also had a blank refill portion of the prescription. Both prescriptions lacked a patient address. [Tr. 48–49; Gov't Exh. 4 at 98]. There was no evidence that these ''red flags'' were resolved prior to dispensing the drug. [Tr. 49]. Dr. Witte opined that these two prescriptions should not have been dispensed, given the unresolved ''red flags.'' [Tr. 49].

In her review of prescriptions, Dr. Witte noted that on several occasions a controlled substance was dispensed, and the patient was given back the hard copy of the prescription. [Tr. 51–55, 165; Gov't Exh. 3 at 13–14, 19–20]. Such a practice is not acceptable in the field of pharmacy and creates a risk of diversion [19]. [Tr. 52, 54–55].[20]

On a prescription dated December 2, 2010, the physician had stamped ''All or None.'' The prescription was for three drugs, and the only drug dispensed was the controlled substance. [Tr. 56–57; Gov't Exh. 3 at 15–16]. Also, the physician's DEA number was missing on the prescription, and the patient's address was missing. [Tr. 56]. Such a prescription would have been a ''red flag'' which should have been resolved prior to dispensing the medication. Per Dr. Witte, no resolution was annotated on the prescription. [Tr. 57]. She opined that this prescription should not have been dispensed in the manner utilized by the Respondent's pharmacist. [Tr. 57; *see also* Gov't Exh. 3 at 17–18 and Tr. 57–59].

Dr. Witte reviewed another prescription dated December 15, 2010, which contained a total of five drugs. The patient only requested that the controlled substances be dispensed. [Tr. 59–60; Gov't Exh. 3 at 57–58]. Such conduct would be a ''red flag'' and should have been resolved prior to dispensing the medication. Dr. Witte saw no evidence that the problems were resolved prior to dispensing the medication, and she opined that these controlled substances should not have been dispensed prior to resolving these ''red flags.'' [Tr. 60]. Likewise, two patients sharing the same address presented prescriptions with multiple medications, and the pharmacist only filled the controlled substance. [Tr. 61–63; Gov't Exh. 4 at 235–36]. Again, such conduct would be a ''red flag,'' and the prescription fails to indicate any action taken to resolve the ''red flag'' prior to dispensing the controlled substance. [Tr. 62].

Dr. Witte also reviewed two prescriptions written for the same patient. One was dated November 23, 2010, and the second prescription was dated December 9, 2010, and both prescriptions contained controlled substances. [Tr. 65; Gov't Exh. 3 at 70, 76]. The prescriptions were written by different practitioners. After filling the controlled substance on the November 23, 2010 prescription, the pharmacist handed back the prescription to the patient. Such conduct would allow the patient to fill the November 23 prescription at another pharmacy, and then fill the December 9 prescription at yet another pharmacy. Although the controlled substance was dispensed from the November

[18] Such prescriptions would be for a ''drug cocktail.'' [Tr. 40–41; Gov't Exh. 9 at 66].

[19] However, on cross-examination, DI Ramirez credibly testified that she had not investigated whether or not these prescriptions resulted in duplicate filling of controlled substances. [Tr. 165].

[20] Dr. Witte also credibly testified that on one prescription an annotation stating ''Pt took hard copy back'' meant that the patient took back the hard copy of the prescription. [Gov't Exh. 3 at 70]. However, since the comment was not initialed, Dr. Witte did not know who had written the comment. [Tr. 99–100]. I find that it is a reasonable assumption, based on the totality of the prescriptions presented and the lack of any challenge from the Respondent concerning this notation, that the annotation was made by an employee of the Respondent. [Tr. 109–111].

23 prescription, the prescription did not contain a notation of the dispensing that would alert any other pharmacist that that drug had already been dispensed. [Tr. 65–66]. Such prescriptions, as handled by the Respondent's pharmacist, presented ''red flags,'' and the prescriptions had no notations demonstrating that the ''red flags'' were resolved prior to the dispensing of the controlled substances. [Tr. 67]. The prescription on December 9, 2010, should not have been dispensed. [Tr. 67].

Lastly, Dr. Witte reviewed three prescriptions containing controlled substances written for the same patient, who was also an employee of the Respondent. The patient had a prior conviction for drug distribution, and such prescriptions would raise ''red flags.'' [Tr. 67–68; Gov't Exh. 4 at 84–89, Gov't Exh. 10]. The fact that the prescriptions contained multiple medications, and that the patient only filled some of the controlled substances, Dr. Witte found these ''red flags'' should have been resolved prior to dispensing the controlled substances. The patient's criminal conviction for drug distribution would add another ''red flag'' for these prescriptions. [Tr. 68]. The prescriptions did not contain any annotation that the pharmacist resolved the ''red flags'' prior to dispensing the controlled substances. In Dr. Witte's view, these controlled substances should not have been dispensed in this manner. [Tr. 68–69].

Overall, Dr. Witte opined that the Respondent did not exercise its corresponding responsibility to ensure that prescriptions for controlled substances were issued for a legitimate medical purpose. [Tr. 69].

D. Prescription Issues

After reviewing the prescriptions found in Government Exhibit 3, DI Ramirez credibly testified that she found six instances when the controlled substances were filled and the non-controlled substances were not filled. [Tr. 111]. Mr. Lekwa stated that for one of those prescriptions, he had called the doctor concerning the prescription. He had placed his notes from the call in the computer, not on the back of the prescription. [Tr. 205–08; Gov't Exh. 3 at 16].

Further, DI Ramirez found five examples in Government Exhibit 3 of prescriptions that did not contain a signature from the prescribing practitioner. [Tr. 114]. DI Ramirez also found approximately 44 prescriptions in Government Exhibit 3 that failed to contain a patient address. [Tr. 115–16]. She also found approximately 11 prescriptions in Government Exhibit 3 that had a missing or incorrect DEA number. [Tr. 116]. DI Ramirez also found 4 prescriptions where the name on the front of the prescription for controlled substances did not match the name on the dispensing label. [Tr. 117–19; see also Tr. 121–22, Gov't Exh. 4 at 192–93].

After reviewing Government Exhibit 4, DI Ramirez found approximately 125 prescriptions for controlled substances without a patient address. [Tr. 124]. This exhibit also contained approximately 157 prescription labels for controlled substances that identified the wrong prescribing practitioner. [Tr. 116–17, 124–25; Gov't Exhs. 3, 4]. There were also 22 prescriptions for controlled substances that either had a missing or incorrect prescriber DEA number. [Tr. 125].

DI Ramirez also credibly testified that 98 prescriptions purportedly from a Dr. Leo Edwards had a signature stamp rather than a manual signature. [Tr. 141–44; Gov't Exh. 8, 9]. When asked by DI Ramirez, Dr. Edwards confirmed that he had used a signature stamp on his prescriptions. [Tr. 144; Gov't Exh. 8, 9].

On at least 22 occasions, the Respondent's personnel filled controlled substance prescriptions and then returned the original paper prescriptions to the customer. [Tr. 109–10; Gov't Exh. 3 at 5, 11, 13, 19, 28, 35, 37, 39, 41, 43, 45, 47, 53, 70, 75, 76, 78, 82, 84, 90, 92, and 104].

DI Ramirez found several instances in which controlled substances were provided to customers without any valid prescription whatsoever for that individual. For example, Respondent's personnel distributed alprazolam to customer T.J., but the only record attached to the prescription label was a prescription for hydrocodone issued to customer R.S. [Tr. 117; Gov't Exh. 3 at 99–100; *see also* Tr. 118–19, 121–22; Gov't Exh. 3 at 103, 111; Tr. 121–22; Gov't Exh. 4 at 192–93].

DI Ramirez did not discover any evidence of any outright forged or fraudulent prescriptions. [Tr. 168]. She also did not identify any clientele that were coming from out of state. [Tr. 168].

E. The Audit

On the date that the Administrative Inspection Warrant was served, November 9, 2011, DI Ramirez conducted an audit of different dosages of controlled substances. [Tr. 136, 159; Gov't Exh. 13]. The starting point for the audit was the Respondent's inventory of October 30, 2010 [21], and the ending date of the audit was November 8, 2011. [Gov't Exh. 13]. DI Ramirez took a count of seven different strengths of controlled substances that were on-hand at the pharmacy on the date of the audit. She also added the receipts of each dosage for the audit timeframe to get a ''total accounted for'' amount. [Tr. 137; Gov't Exh. 13]. Next, DI Ramirez obtained sales and distribution records for the dosages of controlled substances sold and added that figure to the total on-hand on the day of the audit to show what the pharmacy could account for in their records. As a result of this audit, the Respondent had an overage of 445 Methodone 10 mg. tablets, a shortage of 27,344 ml. of Promethazone with codeine (or 929 ounces), an overage of 1,508 Hydrocodone 5 mg. tablets, an overage of 18,721 Hydrocodone 7.5 mg. tablets, a shortage of 3,445 Hydrocodone 10 mg. tablets, a shortage of 43,359 Alprazalam 1 mg. tablets, and a shortage of 7,769 Alprazalam 2 mg. tablets. [Tr. 138–140; Gov't Exh. 13]. DI Ramirez did not discuss these results with Mr. Lekwa, Respondent's owner. [Tr. 139]. At the hearing, Mr. Lekwa gave no explanation for these discrepancies.

[21] DI Ramirez confirmed that an annual inventory was conducted at the Respondent pharmacy. When DI Ramirez executed the Administrative Inspection Warrant, Mr. Lekwa, owner of the Respondent, was in the process of conducting his annual inventory. [Tr. 161].

F. Recordkeeping Deficiencies

When DI Ramirez reviewed the Respondent's receiving invoices, she noted that the dates of the receipt of the controlled substances and verification of the quantities received were missing. [Tr. 146; Gov't Exh. 5]. Of these eight invoices, there were 19 entries for controlled substances, and the required annotations were lacking. [Tr. 146; Gov't Exh. 5]. This pattern was repeated for other invoices. [Tr. 148–51; Gov't Exh. 6, 7]. Also, in looking at the DEA 222 forms, which are used to record the receipt of Schedules I and II controlled substances, DI Ramirez also noted that the forms lack what was received, the quantity received, and the date that the controlled substances were received by the pharmacy. [Tr. 152; Gov't Exh. 12].

G. Hiring of a Prior Felon

A.G. worked for the Respondent from 2008 to September of 2013. [Tr. 14; Gov't Exh. 11, 14]. He worked as a delivery driver, and he delivered controlled substances as part of his work responsibilities. [Tr. 15, 127–28].

In 1989, A.G. was convicted of distribution of crack cocaine. [Tr. 15–16]. This was a felony conviction. [Tr. 16, 1321–33; Gov't Exh. 10].

Mr. Lekwa asked A.G. to retrieve a document showing his criminal conviction, and A.G. went to the Texas Department of Public Safety and obtained a document that he subsequently provided to Mr. Lekwa. [Tr. 16, 20; Resp't Exh. 1]. The document related that ''The criminal history record file of the San Antonio Police Department did not reveal at this time any arrest information on the above-named individual.'' [Resp't Exh. 1]. However, A.G.'s conviction occurred in Waco, Texas. [Tr. 24].

At the hearing, Mr. Lekwa admitted that he had not contacted the City of San Antonio Police Department or any county in the state of Texas to get a criminal background check on A.G. [Tr. 202].

In July of 2013, DI Ramirez told Mr. Lekwa about A.G.'s conviction, but Mr. Lekwa continued to employ A.G. until September of 2013. [Tr. 132].

H. Mr. Lekwa

Mr. Lekwa, the pharmacist in charge and the owner of the Respondent, graduated from Texas Southern University in 1993. [Tr. 181]. English is a second language for him. [Resp't Br. at 18]. He is licensed in Texas as a pharmacist. [Tr. 182]. He worked for Walgreens for ten years, first as a pharmacist and then as a pharmacy manager. [Tr. 181]. He opened the Respondent in 2003. [Tr. 186]. The Respondent is a franchise, and the franchise agreement provided that the company would do the site layout, would provide financing at a low interest rate, would assist in marketing the Respondent, and would provide training. The company also has consultants for the Respondent to consult. [Tr. 187–88].

Mr. Lekwa hired a permanent pharmacist, rather than using relief pharmacists like in the past. [Tr. 189]. He also trains the pharmacy technicians to ensure they follow

the DEA requirements. [Tr. 189]. Specifically, he requires the technicians to put the address and phone number on the front of a prescription prior to filling it. [Tr. 190]. As for prescriptions for ''drug cocktails,'' Mr. Lekwa stated that his new procedure is to confirm the prescription with the prescribing practitioner, to annotate that confirmation on the prescription, and to ask the practitioner to fax the diagnosis to the pharmacy. [Tr. 190–91].

Mr. Lekwa also trained his personnel who sign for the receipt of controlled substances to fill out the paperwork completely at the time the controlled substances are actually received, rather than to wait until the end of the month to reconcile the receipts. [Tr. 190].

Mr. Lekwa has served many of his customers for the past ten-plus years. [Tr. 193]. Most of Mr. Lekwa's clients are elderly and use Medicaid or Medicare for their prescriptions. [Tr. 192]. Some of his customers do not have insurance. [Tr. 192]. Because of money constraints, some of his customers request to fill part of their prescription on one day and to return another day to purchase the rest of the medication. [Tr. 192]. Now Mr. Lekwa advises such customers that the patient has to have the means to purchase all of their prescribed medication at one time. [Tr. 192].

Also, Mr. Lekwa acknowledged that he returned the original prescriptions in some cases to the customer. [Tr. 193–94]. He credibly testified that he was not doing this practice now. [Tr. 194–95].

Mr. Lekwa has never been the subject of an investigation or disciplinary action by any state board. [Tr. 182].

Mr. Lekwa acknowledged that mistakes were made at the Respondent pharmacy. [Tr. 184, 220, 223]. Specifically, after he understood the true nature of A.G.'s criminal record, he fired him. [Tr. 185–86]. He also instructed his personnel to make sure the patient's address and phone number are on the front of the prescription. [Tr. 220]. Mr. Lekwa also testified that he did not send DEA any kind of correspondence indicating that he accepted responsibility for any kind of misconduct. [Tr. 200]. Mr. Lekwa testified that he instituted new policies and procedures. Specifically he reviews the Medicine Shoppe manual with each of his employees. He also keeps the manual updated.[22] [Tr. 214–15].

IV. CONCLUSIONS OF LAW AND DISCUSSION

A. Position of the Parties

1. The Government's Position

The Government seeks revocation of the Respondent's Certificate of Registration because to continue its registration would be against the public interest. [Gov't Br. at 30]. Specifically, the Government argues that DEA is bound by agency precedent to revoke Respondent's DEA registration. Citing to DEA final orders, the Government asserts that the Respondent violated state and Federal law by failing to exercise its corresponding responsibility to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose, as required by the Controlled Substances Act and the implemented regulations. [Gov't Br. at 13]. The Government further argued that the Respondent repeatedly filled facially invalid prescriptions, failed to maintain adequate records, and failed to keep an accurate inventory of the controlled substances it purchased. [Gov't Br. at 13–14]. Lastly, the Respondent violated Federal law by employing a convicted drug felon in a position where the felon had access to controlled substances. [Gov't Br. at 14].

Next, the Government asserts that the Respondent dispensed controlled substances despite the unresolved red flags. [Gov't Br. at 14]. Specifically, the Government argues that the Respondent's personnel distributed controlled substances pursuant to prescriptions that contained one or more unresolved ''red flags.'' Dr. Witte's testimony establishes this fact. [Gov't Br. at 14–16].

Additionally, the Government argues that the Respondent's failure to keep accurate records violated Federal statutory and regulatory provisions that require an accurate inventory of controlled substances. [Gov't Br. at 16]. The inadequacy of the Respondent's system is evidenced by the audit conducted by the DEA resulting in large shortages and overages. [Gov't Br. at 17]. The Respondent's records were also deficient because Mr. Lekwa failed correctly to record complete invoices of controlled substances received. [Gov't Br. at 17–18]. Lastly, the Respondent, by permitting customers to retain their original prescriptions, violated Federal regulations that require the Respondent to maintain the paper prescription for Schedules III, IV, and V controlled substances at the registered location. [Gov't Br. at 18].

The Government also argues that the Respondent violated DEA regulations by hiring A.G., a felon convicted of a drug-related crime, and by failing to do a proper and thorough background check. [Gov't Br. at 19]. Also, the Respondent failed to prove that it accepted responsibility for its actions or to demonstrate that it will not engage in future misconduct. Further, a Respondent's lack of candor and inconsistent explanations may serve as a basis for denial of a registration. [Gov't Br. at 20–24].

The Government asserts that the Respondent's practices significantly increased the risk of diversion. [Gov't Br. at 24]. Further, the Respondent has provided insufficient evidence of facts that demonstrate mitigating circumstances. [Gov't Br. at 25].

Lastly, the Government argues that Mr. Lekwa's testimony was not credible and should be given no weight. [Gov't Br. at 28]. The Government states that ''[n]otwithstanding the confusing and contradictory nature of his testimony, Mr. Lekwa's wholesale failure to produce a single written document to support his position militates in favor of finding him to be an incredible witness. . . . Mr. Lekwa has also testified in a manner that was non-responsive, evasive, and internally inconsistent.'' [Gov't Br. at 29].

In light of all of the above, the Government requests that I recommend that the Respondent's Certificate of Registration should be revoked. [Gov't Br. at 30].

2. The Respondent's Position

The Respondent asserts that its Certificate of Registration should not be revoked and any pending applications for renewal should be granted. [Resp't Br. at 23]. First, Respondent asserts that it holds a valid license in the State of Texas, and the State has not made a recommendation in this matter. Thus, factor one of the statutory provision is not an impediment to the Respondent's keeping his registration. [Resp't Br. at 6].

As for factor three, the Respondent states that the record does not contain evidence that the Respondent, its owner, or any pharmacist or key employee of the pharmacy has been convicted of a crime related to the manufacture, distribution, or dispensing of controlled substances. [Resp't Br. at 7].

As for factor two, the Respondent asserts that neither the Respondent, Mr. Lekwa nor any other pharmacist or pharmacy technician employed by Respondent has ever been investigated, disciplined or charged with any violation of state or federal administrative, regulatory, or criminal law. [Resp't Br. at 7].

As for factor four, the Respondent admitted that the Government has met its burden of proof and has shown by a preponderance of the evidence that the Respondent has committed acts inconsistent with the public interest. [Resp't Br. at 8]. Mr. Lekwa testified that the Respondent accepted responsibility for its misconduct. Then he asserted that a qualitative assessment of the Respondent's current practices should occur to determine whether or not sufficient corrective action has been taken to prevent similar occurrences of future misconduct. [Resp't Br. at 8–9].

The Respondent then analyzes the difference between resolvable and unresolvable red flags. As for resolvable red flags, the Respondent asserts that such indicators may be resolved through discussions with patients and prescribers, as well as through the pharmacist's own knowledge of the patient's past history as a customer. [Resp't Br. at 10]. Unresolvable red flags are situations in which ''no amount of information gathered or verification made by the pharmacist could foresee any explanation that would satisfy a Pharmacist's corresponding responsibility under federal law not to fill the scripts.'' [Resp't Br. at 10]. He concludes that ''[r]esolvable red flags, if resolved, are lawful prescriptions. Unresolvable red flags are illegal and substantial evidence of drug diversion.'' [Resp't Br. at 11]. The ''type of red flags that support a finding that Respondent's pharmacists repeatedly and intentionally dispensed prescriptions are those where they had reason to know that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice.'' [Resp't Br. at 12].

The Respondent asserts that now there are policies and procedures in place at Respondent to correct missing or incomplete data on prescriptions. [Resp't Br. at 12]. For example, the Respondent has hired another

[22] The Government made the point that Mr. Lekwa did not bring the manual to the hearing or place it into the record. [Tr. 216].

pharmacist to supervise employees in Mr. Lekwa's absence, and has obtained an independent audit of all records relating to the inventory, to include purchasing, storing, dispensing and recordkeeping practices of the Respondent. [Resp't Br. at 14]. Mr. Lekwa has instituted additional training regimen, has conducted FBI criminal background checks on all of his employees, and has implemented a policy whereby all of the prescribed drugs or none of the prescribed drugs will be dispensed per prescription. [Resp't Br. at 14].

Yet, Mr. Lekwa admits that he dispensed drugs for prescriptions that were suspicious and not resolvable. The Respondent affirms that calling the physician does not immunize the Respondent from its duty to ensure the prescriptions are for a legitimate medical purpose. [Resp't Br. at 13].

The Respondent cites DEA precedent for the proposition that the DEA ''has declined to revoke a registration where non-egregious recordkeeping errors were acknowledged by the pharmacy PIC and remedied promptly.'' *Terese, Inc., d/b/a Peach Orchard Drugs,* 76 Fed. Reg. 46,843, 46,848 (DEA 2011).[23] He then asserted that the flaws in the biannual inventory were non-egregious flaws. Further, the error of receipts and invoices lacking necessary date, acknowledged by the Respondent, was non-egregious. [Resp't Br. at 17].

Next, the Respondent argues that its ''acceptance of responsibility was . . . significant and deserving of great weight and consideration since it occurred before the hearing and presentation of the evidence.'' [Resp't Br. at 17]. It has presented sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility of a continued registration, the Respondent asserts. [Resp't Br. at 17–18]. According to Respondent, ''[t]he evidence shows that the Respondent's continued registration would not threaten the public safety.'' [Resp't Br. at 20].[24] In conclusion, the Respondent asserts that although the Government has met its burden of proof, ''the evidence further shows that Respondent will not commit future acts of misconduct making its continued registration consistent with the public interest.'' [Resp't Br. at 23].

B. Statement of Law and Discussion

Pursuant to 21 U.S.C. § 824(a)(4), the Deputy Administrator[25] may revoke a registration, and deny a pending application for renewal or modification, if he determines that the continuation or issuance of such registration would be ''inconsistent with the public interest'' as determined pursuant to 21 U.S.C. § 823(f). 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 and safety.

21 U.S.C. § 823(f); *see also Alexander Drug Co.,* 66 Fed. Reg. 18,302 (DEA 2001); *Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 Fed. Reg. 75,959, 75,967 (DEA 2000). These factors may be considered in the disjunctive: The Deputy Administrator may properly rely on any one or a combination of these factors, and may give each factor the weight he deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *Liddy's Pharmacy, L.L.C.,* 76 Fed. Reg.48,887, 48,893 (DEA 2011) (citing *Hoxie v. DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall v. DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005)); *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15,227, 15,230 (DEA 2003).

Factors two and four are relevant.

Further, in an action to revoke a registrant's certificate, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 C.F.R. § 1301.44(e). The burden of proof then shifts to the Respondent once the Government has made its prima facie case. *Arthur Sklar, R.Ph., d/b/a King Pharmacy,* 54 Fed. Reg. 34,623, 34,627 (DEA 1989). Specifically, after the Government ''has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present sufficient mitigating evidence to assure the Administrator that [the Respondent] can be entrusted with the responsibility carried by such a registration.''' *Medicine Shoppe,* 73 Fed. Reg. at 387 (quoting *Samuel S. Jackson,* 72 Fed. Reg. 23,848, 23,853 (DEA 2007) (quoting *Leo R. Miller,* 53 Fed. Reg. 21,931, 21,932 (DEA 1988)). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc. v. DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [its] actions and demonstrate that [it] will not engage in future misconduct.'' *Medicine Shoppe,* 73 Fed. Reg. at 387; *see also Jackson,* 72 Fed. Reg. at 23,853*; John H. Kennedy,* 71 Fed. Reg. 35,705, 35,709 (DEA 2006); *Prince George Daniels,* 60 Fed. Reg. 62,884, 62,887 (DEA 1995); *See also Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor'' in the public interest determination)].

1. Prescriptions

Pursuant to the Controlled Substances Act and its implementing regulations, a pharmacy, a prescription-dispensing registrant, has a corresponding responsibility, along with the physician, a prescription-issuing registrant, to ensure the prescription is valid. 21 C.F.R. § 1306.04(a). When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge. *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 Fed. Reg. 62316 (DEA 2012) [hereinafter *CVS*]; *see also United Prescription Services,* 72 Fed. Reg. at 50,407; *Pharmboy Ventures Unlimited, Inc.,* 77 Fed. Reg. 33,770, 33,772 n.2 (DEA 2012) (''DEA has long held that it can look behind a pharmacy's ownership structure 'to determine who makes decisions concerning the controlled substance business of a pharmacy.'''); *S&S Pharmacy, Inc.,* 46 Fed. Reg. 13051, 13052 (DEA 1981) (''the corporate pharmacy acts through the agency of its pharmacist in charge''). Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself. *See U.S. v. One Parcel of Land,* 965 F.2d 311, 316 (7th Cir. 1992) (''Only knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation.'').

The applicable regulations state that the test for the proper prescribing and dispensing of controlled substances is as follows:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

21 C.F.R. § 1306.04(a). Thus, for a prescription to be lawful, it needs to be written for a legitimate medical purpose in the practitioner's usual course of professional practice. *Id.* The pharmacist has a corresponding responsibility to verify the validity of a prescription, and if a prescription seems suspect, the pharmacist has a duty to investigate the prescription to determine its legitimacy. *See CVS,* 77 Fed. Reg. at 62,340–41. The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself. *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. at 384 (finding that a respondent pharmacy was properly charged with violating corresponding responsibility); *United Prescription Services, Inc.,* 72 Fed. Reg. 50397, 50407–08 (2007) (same). *EZRX, LLC,* 69 Fed. Reg. 63,178, 63,181 (DEA 2004) (''DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill their corresponding responsibility in Internet prescribing operations . . . .'')

DEA has consistently interpreted the prescription provision as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ''knows or has reason to know that the prescription was not written for a legitimate medical purpose.'' *Medic-Aid Pharmacy,* 55 Fed. Reg.

[23] The Respondent asserts that Mr. Lekwa has hired a private company to conduct an annual inventory. This fact, however, is not part of the record and the Respondent did not cite any record source for this fact.

[24] The Respondent rebuts the Government's expert witness by asserting that her professional opinion was based upon incomplete information. [Resp't Br. at 20].

[25] The Deputy Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2009).

30,043, 30,044 (DEA 1990). *See also Frank's Corner Pharmacy,* 60 Fed. Reg. 17,574, 17,576 (DEA 1995); *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 Fed. Reg. 4,729, 4,730 (DEA 1990) [hereinafter *Bertolino*]; *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 his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 Fed. Reg. at 4,730 (citations omitted); *see also Sun & Lake Pharmacy, Inc.,* 76 Fed. Reg. 24,523, 24,530 (DEA 2011); *Liddy's Pharmacy, L.L.C.,* 76 Fed. Reg. at 48,893; *East Main Street Pharmacy,* 75 Fed. Reg. 66,149, 66,163 (DEA 2010); *Lincoln Pharmacy,* 75 Fed. Reg. 65,667, 65,668 (DEA 2010); *Bob's Pharmacy,* 74 Fed. Reg. 19,599, 19,601 (DEA 2009). However, the DEA does not require omniscience. *Carlos Gonzalez,* 76 Fed. Reg. 63,118, 63,142 (DEA 2011) (citing *Holloway Distrib.,* 72 Fed. Reg. 42,118, 42,124 (DEA 2007)).

Yet, when an attempted transaction would give rise to suspicion in a ''reasonable professional,'' there is a duty to ''question the prescription[].''*Bertolino,* 55 Fed. Reg. at 4730. The ''reasonable professional'' has been further developed into the ''reasonable pharmacist'' standard. *East Main Street Pharmacy,* 75 Fed.Reg. at 66165; *see also Winn's Pharmacy,* 56 Fed.Reg. 52559, 52561 (DEA 1991). Accordingly, a pharmacist or pharmacy may not dispense a prescription in the face of a red flag (i.e., a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he or it takes steps to resolve the red flag and ensure that the prescription is valid. *East Main Street Pharmacy,* 75 Fed. Reg. at 66,165. Because Agency precedent limits the corresponding responsibility to circumstances which are known or should have been known, *Sun & Lake Pharmacy, Inc.,* 76 Fed. Reg. at 24,530, it follows that, to show a violation of a corresponding responsibility, the Government must establish that: ''(1) The Respondent dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance.'' *CVS,* 77 Fed. Reg. at 62316; *see also Sun & Lake Pharmacy,* 76 Fed. Reg. at 24,532 (finding that pharmacy violated corresponding responsibility when it took no steps to resolve red flags prior to dispensing controlled substances.). The steps necessary to resolve the red flag conclusively is dependent upon the nature of the specific red flag. *CVS,* 77 Fed. Reg. at 62,341.

In support of its allegation that the Respondent has violated its corresponding responsibilities, the Government has introduced evidence that the Respondent pharmacy: (1) dispensed controlled substances without a prescription; (2) dispensed controlled substances when the prescription was ''signed'' using a signature stamp; (3) allowed customers to retain the original controlled substances prescriptions; (4) dispensed controlled substances when the prescription contained irregular dosing instructions; (5) dispensed controlled substances when the prescriptions revealed ''pattern prescribing'' by the physician; (6) dispensed controlled substances when the prescription lacked a patient's address and the physician's DEA registration number; (7) placed a prescription label on the back of the prescription with a physician's name that is not consistent with the name on the front of the prescription; (8) accepted prescriptions where the refill line was blank; and (9) allowed patients with prescriptions containing both controlled and non-controlled substances to fill only the controlled substances' portion of the prescription.

Further, the Respondent also violated state law, which prohibits dispensing controlled substances pursuant to prescriptions that lack a correct DEA registration number, patient address, or prescriber's signature. *See* Tex. Health & Safety Code Ann. § 481.074; Tex. Admin. Code § 13.75.[26]

The record contains no evidence that these ''red flags'' were resolved prior to the dispensing of the controlled substances. A preponderance of the evidence proves that the Respondent violated its corresponding responsibility in the way it dispensed controlled substances pursuant to these defective prescriptions.

2. Recordkeeping Deficiencies

Further, ''[r]ecordkeeping is one of the CSA's central features,'' and ''a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Paul H. Volkman,* 73 Fed. Reg. 30,630, 30,644 (DEA 2008), *aff'd* 567 F.3d 215, 224 (6th Cir. 2009). The statute provides that ''it shall be unlawful . . . to refuse or negligently fail to make, keep, or furnish any record, notification, declaration, order or order form, statement, invoice or information required.'' 21 U.S.C. 842(a)(5). The implementing regulations require that a dispensing registrant must maintain accurate records that include ''the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed'' the controlled substance. 21 C.F.R. § 1304.22(c).

Here, the Respondent's recordkeeping was deficient. The Government presented evidence that the Respondent's invoices were incomplete, and the DEA 222 forms lacked a notation of what was received, the quantity of the controlled substance received, and the date the controlled substance was received by the pharmacy. 21 C.F.R. § 1305.13.[27] Without such records, the pharmacy would be unable to produce an accurate inventory or audit.

DEA, however, attempted to conduct an audit of the Respondent. The results were telling, for the Respondent was unable to accurately account for 27,344 ml. of Promethazone with codeine (or 929 ounces), 1,508 Hydrocodone 5 mg. tablets, 18,721 Hydrocodone 7.5 mg. tablets, 3,445 Hydrocodone 10 mg. tablets, 43,359 Alprazalam 1 mg. tablets, and 7,769 Alprazalam 2 mg. tablets. This inability to account for this significant number of dosage units creates a grave risk of diversion. *Medicine Shoppe,* 73 Fed. Reg. at 367 (finding any amount over 50 dosage units a significant amount); *see also Paul H. Volkman,* 73 Fed. Reg. 30630, 30644 (DEA 2008), *pet. for rev. denied* 567 F.3d 215, 224 (6th Cir. 2009) (finding that ''a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances''). The DEA has also held that it need not find that diversion was the cause of the unaccounted dosage units, to conclude that the Respondent does not maintain effective controls against diversion. *Jack A. Danton, D.O.,* 76 Fed. Reg. 60,900, 60,919 (DEA 2011) (citations omitted). Because the records provided to the DEA failed to correctly record what was accurately received and dispensed, such recordkeeping errors contributed ''to the inability of the Respondent and subsequently the DEA to conduct an accountability audit with accurate results,'' and, thus, violated Federal law. *Jack A. Danton* 76 Fed. Reg. at 60,919.

3. Hiring of a Convicted Felon

DEA regulations provide that a registrant ''shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances.'' 21 C.F.R. § 1301.76(a). Further, the Respondent had a duty to conduct an inquiry concerning any convictions its employees may have on their record. 21 C.F.R. § 1301.90.

Here, the Respondent hired an individual who had a felony conviction for distributing crack cocaine to deliver prescribed drugs, to include controlled substances. Prior to employing this individual, Mr. Lekwa told him to obtain documentation of his criminal record, and A.G. opted to get a criminal background report from the City of San Antonio. This was an insufficient background check, for the applicant had a felony conviction in Waco, Texas, not San Antonio.[28] Indeed, the report itself states that

[26] These statutory and regulatory requirements provide in relevant part that a prescription for a controlled substance must show the quantity of the substance prescribed, the date of the issue, the name, address, and date of birth or age of the patient, the name and strength of the controlled substance prescribed, the directions for use, the name, address, DEA number, and telephone number of the practitioner at the practitioner's usual place of business, and, if the prescription is handwritten, the signature of the prescribing practitioner. Tex. Health & Safety Code Ann. § 481.074.

[27] This regulation provides in relevant part that the pharmacy, as the purchaser, must record on the DEA Form 222 the number of commercial containers furnished on each item, and the dates on which the containers were received.

[28] There was testimony challenging whether the applicant told Mr. Lekwa about his conviction prior to his being hired. I find this irrelevant. The legal point is that Mr. Lekwa did not perform an adequate background check prior to hiring this individual.

it does not include A.G.'s criminal history in any other jurisdiction. [Resp't Exh. 1]. Again, the Government has proved by a preponderance of the evidence that the Respondent violated DEA regulations.

Thus, the burden of production now shifts to the Respondent to demonstrate that it takes full responsibility for its unlawful conduct and that it has put in place remedial measures so that such violations will not happen in the future. *Medicine Shoppe,* 73 Fed. Reg. at 387 (quoting *Samuel S. Jackson,* 72 FR 23,848, 23,853 (DEA 2007)) (holding that a registrant must ''present sufficient mitigating evidence to assure the Administrator that [it] can be entrusted with the responsibility carried by such a registration''); *Leo R. Miller,* 53 Fed. Reg. 21,931, 21,932 (DEA 1988).

On direct examination, Mr. Lekwa took full responsibility for any misconduct attributable to the Respondent. However, on cross examination, Mr. Lekwa presented testimony inconsistent with other testimony in the record. First, he denied that A.G., at the time of his employment interview, told him about his felony conviction for distribution of crack cocaine. A.G. testified to the contrary. Further, DI Ramirez testified that, in July of 2013, she had told Mr. Lekwa about A.G.'s felony conviction, yet Mr. Lekwa denied having this conversation with DI Ramirez. Rather, Mr. Lekwa testified that he had a conversation in September 2013 with DI Ramirez's supervisor. That was when he first learned of the felony conviction, he asserted.

Next, Mr. Lekwa seemed to deny that there was any misconduct when the prescription containing both controlled substance and non-controlled substance entries, as well as a notation of ''all or none,'' was filled by only distributing the controlled substance. Rather, Mr. Lekwa testified that he had contacted the doctor and received permission to fill the prescription in that manner. Yet the record contains no evidence of this verification action. This inconsistent testimony certainly calls into question Mr. Lekwa's genuine remorse for the misconduct proved by the Government.

As for remedial measures, the record contains unrefuted evidence that Mr. Lekwa fired A.G. in September of 2013. Also, Mr. Lekwa testified that he now trains each employee on the procedures to follow in filling a controlled substance prescription. He announced that there was a training manual to help with this training. However, on cross examination Mr. Lekwa stated that the manual was the one the franchise company provided. Although he kept the manual current, there is no evidence that he altered procedures to come into compliance with legal requirements. Rather, Mr. Lekwa testified that the manual was not deficient, but the implementation of the manual provisions was lacking prior to the Order to Show Cause being served. Arguably, this new training would be a meaningful remedial measure. But the record contains no excerpts from the manual to bolster the adequacy of this training.

Next, Mr. Lekwa testified that when he receives a prescription containing a ''drug cocktail,'' he now requires the physician to fax to him confirmation of the diagnosis that resulted in this kind of prescribing. Unfortunately, the record contains no evidence that this procedure has been successfully implemented.

V. CONCLUSION AND RECOMMENDATION

Given the extent of the misconduct and the unreliability of the testimony concerning the acceptance of responsibility, I conclude that the Respondent's registration should be revoked. Accordingly, that is my recommendation based on this record.

Dated: March 24, 2014

Gail A. Randall

Administrative Law Judge

[FR Doc. 2014–23473 Filed 10–1–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Meeting of the Compact Council for the National Crime Prevention and Privacy Compact

AGENCY: Federal Bureau of Investigation, DOJ.

ACTION: Meeting notice.

SUMMARY: The purpose of this notice is to announce a meeting of the National Crime Prevention and Privacy Compact Council (Council) created by the National Crime Prevention and Privacy Compact Act of 1998 (Compact). Thus far, the Federal Government and 30 states are parties to the Compact which governs the exchange of criminal history records for licensing, employment, and similar purposes. The Compact also provides a legal framework for the establishment of a cooperative federal-state system to exchange such records.

The United States Attorney General appointed 15 persons from state and federal agencies to serve on the Council. The Council will prescribe system rules and procedures for the effective and proper operation of the Interstate Identification Index system for noncriminal justice purposes.

Matters for discussion are expected to include:

(1) Civil Fingerprint Image Quality Pilot Program Update

(2) Changes to the Security and Management Control Outsourcing Standards for Channelers and Non-Channelers

(3) National Crime Prevention and Privacy Compact Ratification—Discussion of Ideas to Assist Nonparty States

The meeting will be open to the public on a first-come, first-seated basis. Any member of the public wishing to file a written statement with the Council or wishing to address this session of the Council should notify the Federal Bureau Of Investigation (FBI) Compact Officer, Mr. Gary S. Barron at (304) 625–2803, at least 24 hours prior to the start of the session. The notification should contain the individual's name and corporate designation, consumer affiliation, or government designation, along with a short statement describing the topic to be addressed and the time needed for the presentation. Individuals will ordinarily be allowed up to 15 minutes to present a topic.

DATES: The Council will meet in open session from 9 a.m. until 5 p.m., on November 5–6, 2014.

ADDRESSES: The meeting will take place at the Sheraton Atlanta Hotel, 165 Courtland Street NE., Atlanta, Georgia, telephone (404) 659–6500.

FOR FURTHER INFORMATION CONTACT: Inquiries may be addressed to Mr. Gary S. Barron, FBI Compact Officer, Module D3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306, telephone (304) 625–2803, facsimile (304) 625–2868.

Dated: September 23, 2014.

Gary S. Barron,

FBI Compact Officer, Criminal Justice Information Services Division, Federal Bureau of Investigation.

[FR Doc. 2014–23463 Filed 10–1–14; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility to Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may