therefore not entitled to maintain her DEA registration. *See* 21 U.S.C. 802(21), 823(f), and 824(a)(3). Accordingly, I will order that her registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration MH2194176 issued to Devra A. Hamilton, A.P.N., be, and it hereby is, revoked. I further order that any pending application of Devra A. Hamilton, A.P.N., to renew or modify her registration, be, and it hereby is, denied. This Order is effective September 17, 2015.

Dated: August 10, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–20348 Filed 8–17–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: IRIX Manufacturing, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before October 19, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on March 30, 2015, IRIX Manufacturing, Inc., 309 Delaware Street, Building 1106, Greenville, South Carolina 29605 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to manufacture the above-listed controlled substances as Active Pharmaceutical Ingredient (API) for clinical trials.

Dated: August 10, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–20285 Filed 8–17–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Arthur H. Bell, D.O.; Decision and Order

On July 15, 2014, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Arthur H. Bell, D.O. (Respondent), of Covington, Kentucky. GX 1, at 1. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a practitioner on multiple grounds, including that he had materially falsified his application for a registration, as well as that he had committed acts which render his registration inconsistent with the public interest. *Id.* at 1–2 (citing 21 U.S.C. 823(f) and 824(a)(1)).

As for the material falsification allegation, the Show Cause Order alleged that on November 9, 2011, Respondent had voluntarily surrendered his previous DEA Registration. *Id.* The Order then alleged that on March 14, 2013, Respondent applied for a new DEA registration, but materially falsified the application when he ''answered 'no' to question which asked, '[h]as the Respondent ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?''' *Id.*

As for the allegations that Respondent had committed acts which render his registration inconsistent with the public interest, the Show Cause Order alleged that Respondent violated federal law by issuing controlled substance prescriptions when he ''no longer possessed a DEA registration.'' *Id.* at 2 (citing 21 CFR 1306.03(a)). More specifically, the Order alleged that on May 5, 2012, Respondent had issued a prescription for 60 tablets of Lyrica 75 mg, a schedule V controlled substance, and on September 12, 2012, Respondent had issued a prescription for Zutripro 120 ml, a schedule III controlled substance. *Id.*

The Show Cause Order also alleged that from July 11, 2011 through November 4, 2011, Respondent ''dispensed controlled substances on behalf of Care Plus Medical Group (CPMG), a purported pain management clinic formerly located in Creve Coeur, Missouri, [which] was owned by Scott Whitney.'' *Id.* The Order alleged that prior to beginning his employment with CPMG, Respondent arranged with Whitney to order schedule II controlled substances under his previous registration and that ''[t]o that end, . . . Whitney sent 20 DEA 222 forms to [Respondent's] residence, and asked that [he] pre-sign them so that controlled substances could be ordered on behalf of CPMG.'' *Id.* The Order then alleged that Respondent ''pre-signed the forms, dated them . . . and mailed them to . . . Whitney . . . [who] then used one . . . to place orders for oxycodone 30 mg and oxycodone 10/325 mg.'' *Id.* The Order alleged that this violated federal law because it ''authoriz[ed] . . . Whitney to place an order for controlled substances under [Respondent's] previous . . . registration without executing a power of attorney for . . . Whitney.'' *Id.* (citing 21 CFR 1303.05(a)).

Next, the Show Cause Order alleged that on October 28, 2013, Respondent falsified his application for his Ohio medical license, when he failed to disclose that he had previously surrendered his DEA registration. *Id.* at 1–2. The Order further alleged that this ''conduct evidences a lack of candor to Ohio licensing authorities.'' *Id.* (citing 21 U.S.C. 823(f)(5)).

Finally, the Show Cause Order notified Respondent of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence of failing to elect either option. *Id.* at 2–3 (citing 21 CFR 1301.43). The Government also included with the Order a sample Request for Hearing form. *Id.* at 4.

The Government represents that on July 21, 2014, the Show Cause Order was served on Respondent by certified mail, and there is no dispute that service occurred, as on August 8, 2014, the Hearing Clerk, Office of Administrative Law Judges, received a letter from Respondent. Request for Final Agency Action, at 3; *see also* GX 10. In the letter, Respondent responded to each of the Government's allegations. GX 10, at 1–2. Respondent did not, however, request a hearing.

Based on Respondent's letter, I find that he had waived his right to a hearing on the allegations. 21 CFR 1301.43(c). However, pursuant to 21 CFR 1301.43(c), I deem Respondent's letter to be his ''written statement [of] position on the matters of fact and law involved'' in the proceeding.

Thereafter, on December 12, 2014, the Government submitted its Request for Final Agency Action along with the Investigative Record. Having reviewed the Government's evidence as well as Respondent's Statement of Position, I make the following findings of fact.

Findings

Respondent's Registration and Licensing Status

Respondent previously held DEA Certificate of Registration BB6473538, pursuant to which he was authorized to dispense controlled substances in schedules II–V as a practitioner, at Care Plus Medical Group (CPMG) in Creve Coeur, Missouri. GX 3. According to a DEA Diversion Investigator (DI), following an investigation into CPMG by DEA, Respondent voluntarily surrendered his registration on November 9, 2011, and on the form manifesting the surrender, Respondent acknowledged that he was surrendering his registration ''[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances.'' GX 5, at 1; GX 11, at 3. The next day, Respondent's registration was retired by the Agency. GX 2, at 2.

On January 12, 2012, Respondent applied for a new registration. GX 12, at 2. However, on March 5, 2012, following an interview with DEA Investigators regarding his activities at CPMG, Respondent withdrew this application. *Id.* at 2–3.

On March 14, 2013, Respondent submitted a new application, seeking authority to dispense controlled substances in schedules II through V, at the registered location of Hometown Urgent Care, 4387 Winston Ave, Covington, KY. GX 7, at 1. It is this application which is at issue in this proceeding.

On the application, Respondent was required to answer four questions, including number two, which asked: ''Has the Respondent ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' *Id.* at 2. Respondent answered ''N'' for no. *Id.*

Respondent also holds valid medical licenses in Ohio and Kentucky. These licenses expire on July 1, 2017 and February 29, 2016, respectively.[1]

The Investigation of Respondent

According to a DI, Respondent was previously employed at CPMG from July 11, 2011 through November 4, 2011. GX 11, at 3 (Declaration of Diversion Investigator). CPMG was owned by Scott Whitney, and Respondent was the clinic's sole physician. *Id.* at 2.

In August 2011, another DI received an anonymous tip alleging that CPMG was diverting controlled substances. *Id.* The tipster alleged that individuals could walk into the clinic without an appointment, could consult with a doctor in exchange for $250 in cash, that CPMG did not accept insurance, and that CPMG ''had an in-house pharmacy.'' *Id.* Subsequently, the DI determined that Mr. Whitney ''had prior ownership interests in other pain clinics in the State of Florida'' that had ''dispensed oxycodone'' but had ''since closed.'' *Id.*

On November 9, 2011, the DI interviewed Respondent. *Id.* at 3. Respondent told the DI that at some point prior to starting at CPMG, Whitney had requested that Respondent pre-sign DEA–222 Forms, which are required to order schedule II drugs such as oxycodone, *see* 21 U.S.C. 828(a), ''as a way to start the business.'' *Id.* Whitney mailed approximately twenty DEA–222 forms to Respondent, who signed them and mailed them back to Whitney. *Id.*

According to the DI, Whitney used at least one of the pre-signed order forms to place orders for 2,000 du of oxycodone 30 mg and 1,000 oxycodone 10/325 mg from State Pharmaceuticals, Inc. on June 29, 2011. *Id., see also* GX 4. The DI also found that Respondent ''authorized [] Whitney to place an order for controlled substances under his DEA . . . registration without executing a power of attorney for him,'' a violation of 21 CFR 1305.05(a). *Id.*

After the conclusion of the interview, the DI asked Respondent if he would voluntarily surrender his DEA registration. *Id.* at 3. Respondent agreed to do so, and executed a Voluntary Surrender Form. *Id.; see also* GX 5.

On January 11, 2013, Respondent submitted an application for renewal of his Ohio medical license. GX 6, at 1. The application included a question which asked: ''Have you surrendered, consented to limitation of, or to suspension, reprimand or probation concerning, a license to practice any healthcare profession or state or federal privileges to prescribe controlled substances in any jurisdiction other than Ohio?'' *Id.* at 3. Respondent answered ''NO.'' *Id.*

As noted above, on March 14, 2013, Respondent applied for a new registration. Thereafter, on May 22, 2013, a DI queried the Ohio Automated Rx Reporting System (OARRS), using Respondent's previously surrendered DEA registration (BB6473538). GX 12, at 3. The OARRS report showed that Respondent had issued two controlled substance prescriptions after he surrendered his registration: 1) on May 5, 2012, for 60 tablets of Lyrica 75 mg (a schedule V controlled substance) on May 5, 2012; and 2) on September 12, 2012, for Zutripro 120 ml (a schedule III cough syrup containing hydrocodone). *Id.* at 3–4.

The DI then obtained copies of both prescriptions. *Id.* at 4. The first prescription, which is dated May 5, 2012, was for 60 capsules of Lyrica 75 mg, and was printed on a prescription form for Urgent Care of Fairfield, including its street address. GX 8. The prescription includes a handwritten signature of ''Art Bell DO'' above ''Art Bell DO,'' which is printed below the signature line. *Id.* However, no DEA number appears on the prescription. *Id.*

The second prescription, which is dated September 12, 2012, was for ''Bromfed DM 2mg-30mg-10mg/5ml Syrup,'' a non-controlled drug, and was also on a printed form bearing the name of Urgent Care of Fairfield and its address. GX 9. However, the drug name is lined-out and the word ''Zutripro'' is handwritten above it. *Id.* Zutipro is a schedule III controlled substance which contains hydrocodone. As with the previous prescription, the signature line contains a handwritten signature of ''Art Bell DO,'' with ''Art Bell DO'' printed below the signature line. *Id.* Also written on the prescription is the notation: ''per Katie Allen.'' Again, no DEA number appears on the prescription.[2] *Id.* According to the DI, on the dates that each prescription was issued, Respondent was working at

[1] The Government provided copies of online license searches which show that Respondent is licensed as an osteopathic physician in Ohio and Kentucky.

[2] GX 8 and GX 9 also include copies of the dispensing labels for each prescription.

Urgent Care of Fairfield in Hamilton, Ohio. GX 12, at 4.

Respondent's Statement of Position

In his response to the Order to Show Cause, Respondent stated that he re-applied for a DEA registration on March 14, 2013, ''not as a physician seeking authorization to handle controlled substances in Schedules II through V at a proposed registered address of 4387 Winston Avenue, Covington, Kentucky [] but to satisfy insurance company requirements.'' GX 10, at 1 (emphasis in original). He asserted that ''many medical facilities require that their physicians have a DEA registration, and that ''I hardly ever wrote for any controlled substances prior to my employment with Care Plus Medical Group.'' *Id.*

Regarding the allegation that he materially falsified his DEA application when he provided a ''no'' answer to question two, Respondent asserted that he provided the answer because ''I voluntarily surrendered my registration.'' *Id.* (emphasis in original.) He then maintained that ''the DEA agent advised me to do so stating that it most likely would be returned to me within 2–4 weeks. Since I voluntarily surrendered the registration and no one mentioned (for cause), I answered the question ''no.'' *Id.* (emphasis in original). Respondent added that he ''misunderstood and was completely unaware that by voluntarily surrendering one's DEA registration equals voluntarily surrendering (for cause).'' *Id.* (emphasis in original). He further stated that ''semantics may have played a part in the confusion of this situation. Please know that the thought never crossed my mind to commit a fraudulent act. I apologize for the confusion.'' *Id.*[3]

As for the two prescriptions, Respondent denied having issued them. More specifically, he stated: ''As for the two prescriptions that I allegedly wrote for Lyrica 75 mg and Zutripro 120ml. I know nothing about this.'' *Id.* He then questioned whether there ''was a possibility that a substitute was given by the nurse without my approval because insurance would not cover the non-narcotic prescription that I had originally written?'' *Id.* He then added that ''I suppose anything is possible in this circumstance, but rest assured, that I have not written any prescriptions for controlled substances since the surrendering of my DEA registration on November 9, 2011.'' *Id.*

Respondent did admit that he pre-signed 20 DEA–222 forms and that he sent the forms to Whitney and failed to execute a power of attorney authorizing Whitney to order the drugs. However, he then contended that the allegation[4] that he ''arranged with Mr. Whitney to order Schedule II controlled substances under [his] previous DEA registration'' was not a correct statement, because ''Mr. Whitney arranged this with me—I did not know how to order controlled substances.'' *Id.* Continuing, Respondent wrote: ''[a]gain, that action was pure naiveté and ignorance of the law on my part'' and ''saying I'm sorry does not even begin to express my remorse . . . [n]or does it alleviate the feelings of stupidity for my actions because of the poor judgment that I used on that day.'' *Id.*

Respondent concluded his letter by stating that he ''did not knowingly tell lies, nor . . . intentionally try to deceive anyone.'' *Id.* He expressed the hope that his letter ''conveys [his] remorse'' and stated that he ''would also like to be able to retire in a few years with my good name intact and above reproach.'' *Id.*

Discussion

Section 303(f) of the Controlled Substances Act provides that an application for a practitioner's registration may be denied upon a determination ''that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the CSA requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The Applicant's experience in dispensing . . . controlled substances.

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

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

(5) Such other conduct which may threaten the public health and safety. *Id.*

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman,* 567 F.3d 215, 222 (6th Cir. 2009) (quoting *Hoxie,* 419 F.3d 477, 482 (6th Cir. 2005))).

''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009).

Also, pursuant to section 304(a)(1), the Attorney General is authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. 824(a)(1). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See The Lawsons, Inc.,* 72 FR 74334, 74337 (2007); *Anthony D. Funches,* 64 FR 14267, 14268 (1999); *Alan R. Schankman,* 63 FR 45260 (1998); *Kuen H. Chen,* 58 FR 65401, 65402 (1993).

Thus, the allegation that Respondent materially falsified his application is properly considered in this proceeding. *See Samuel S. Jackson,* 72 FR 23848, 23852 (2007). Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *The Lawsons,* 72 FR at 74338; *cf. Bobby Watts, M.D.,* 58 FR 46995 (1993).

The Government has ''[t]he burden of proving that the requirements for . . . registration . . . are not satisfied.'' 21 CFR 1301.44(d). Having considered all of the public interest factors, as well as the separate allegation that Respondent materially falsified his application for a DEA registration, I conclude that the Government has established a *prima facie* case to deny his application. While I have considered Respondent's

[3] As for the false answer he provided on the application for his Ohio license, Applicant stated that ''the renewal of my application for an Ohio license was an oversight'' and that he had re-applied for renewal of his Kentucky and Missouri licenses and stated on both ''that I had voluntarily surrendered my DEA registration.'' GX 10, at 2. He wrote that ''I mistakenly thought I had checked the box that said I had voluntarily surrendered my DEA registration. . . . Therefore, I checked the box asking 'if anything had changed since my last renewal?' 'no'. [sic] I did not intend to deceive anyone. It was an honest mistake for which I apologize.'' *Id.*

[4] This statement appears as an allegation in the Order to Show Cause. *See* GX 1, at 2.

Statement of Position, I do not find his expressions of remorse persuasive and hold that he has not produced sufficient evidence to refute the Government's *prima facie* case. Accordingly, I will order that his application be denied.

Material Falsification

As found above, on March 4, 2013, Respondent applied for a new registration and answered ''N'' or no to the question: ''[h]as the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' Respondent's answer was false because on November 9, 2011, he voluntarily surrendered his DEA registration following an interview with a DEA Investigator regarding his activities at CPMG, during which he admitted to signing schedule II order forms while failing to execute a power of attorney as required under DEA's regulation. He then provided those forms to CPMG's owner, thereby by allowing the latter to order 2,000 du of oxycodone 30 and 1,000 du of oxycodone 10/325.

This was a violation of DEA regulations and federal law. *See* 21 U.S.C. 842(a)(5) (''It shall be unlawful for any person . . . to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter.''); 21 CFR 1305.04(a) (''Only persons who are registered with DEA under section 303 of the Act . . . to handle Schedule I or II controlled substances . . . may obtain and use DEA From 222 . . . for these substances.''); *id.* § 1305.05(a) (''A registrant may authorize one or more individuals . . . to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual. . . .'').

Respondent nonetheless asserts that he misunderstood the question. He claims that because he ''voluntarily surrendered'' his registration'' and ''no one mentioned (for cause),'' he did not believe that he had surrendered his registration ''for cause.'' However, the circumstances surrounding the interview during which he surrendered his registration, coupled with the language of the voluntary surrender form on which Respondent acknowledged that he was surrendering his registration ''[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances'' GX 5, at 1, are sufficient to support the conclusion that Respondent surrendered his registration ''for cause.''

I also conclude that Respondent's answer was materially false. As the Supreme Court has explained, ''[t]he most common formulation'' of the concept of materiality ''is that a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed.'' *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956)) (other citation omitted); see also *United States* v. *Wells,* 519 U.S. 482, 489 (1997) (quoting *Kungys,* 485 U.S. at 770).

''[I]t has never been the test of materiality that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation, but rather, whether the misrepresentation or concealment was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.'' *Kungys,* 485 U.S. at 771. While the evidence must be ''clear, unequivocal, and convincing,'' the ''ultimate finding of materiality turns on an interpretation of the substantive law.'' *Id.* at 772 (int. quotations and citations omitted).

Notwithstanding that the Agency did not grant his application, Respondent's false answer to question two was clearly ''capable of affecting'' the decision of whether to grant his application because he surrendered his registration in response to allegations that he violated DEA regulations, and under the public interest standard, the Agency is required to consider the Applicant's ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(f)(4). Accordingly, I conclude that Respondent materially falsified his March 2013 application for registration.

In his statement, Respondent contends that ''semantics may have played a part in the confusion of this situation. Please know that the thought never crossed my mind to commit a fraudulent act. I apologize for the confusion.'' GX 10, at 1.

Respondent's explanation is not persuasive. Here, the evidence also shows that when Respondent applied for his Ohio medical license, the State's application contained the following question: ''Have you surrendered, consented to limitation of, or to suspension, reprimand or probation concerning . . . state or federal privileges to prescribe controlled substances in any jurisdiction other than Ohio?'' GX 6, at 3. Respondent, however, answered ''NO.'' *Id.* Notably, in contrast to the question on the DEA application, the Ohio question did not ask whether he surrendered ''for cause'' and thus presented no issue of—in Respondent's view—semantics. Further, Respondent does not claim that he was confused by the question.[5] *Id.* Yet Respondent still provided a false answer to the Ohio question. Thus, I reject his claim of confusion and conclude that his false answer on the Ohio application is probative of his intent in answering the DEA question and that his intent was fraudulent. *Cf.* Fed. R. Evid. R. 404(b)(2).

This conclusion finds further support in the circumstances surrounding the March 5, 2012 interview, which resulted in his withdrawal of the January 5, 2012 application. While the Government did not submit any evidence as to whether Respondent truthfully answered Question Two on this application, a DEA Investigator provided a sworn statement that on March 5, 2012, he interviewed Respondent regarding his activities at CPMG.[6] *See* GX 12, at 2. According to the DI, ''[a]t the conclusion of the interview, DEA investigators informed [Respondent's] legal counsel that [he] could face criminal charges based on his previous handling of controlled substances on behalf of CPMG.'' *Id.* at 2–3. Thereafter,

[5] Rather, Respondent asserts that his answer on the Ohio medical license application ''was an oversight,'' that he ''mistakenly thought I had checked the box that said I had voluntarily surrendered my DEA registration,'' and that ''I checked the box asking 'if anything had changed since my last renewal?' 'no.' '' GX 10, at 2. However, Respondent filed his Ohio medical license application on January 11, 2013, and according to the Web site of the State Medical Board, ''Doctors of Osteopathic Medicine [DOs] are required to renew their licenses biennially in order to maintain an active certificate to practice.'' *See http://www.med.ohio.gov/RenewalCME/DoctorofOstepathicMedicine(DO).aspx.*

As found above, Respondent surrendered his DEA registration on November 9, 2011, and given that his Ohio license was good for two years, I conclude that his previous Ohio application was filed before he surrendered his DEA registration. Thus, at the time he filed his Ohio medical license application, something ''had changed since [his] last renewal.'' GX 10, at 2. Moreover, the Ohio application clearly instructed: ''Please review all information you have provided. Click on the 'Review' button to change any information given. . . .'' GX 6, at 2. The form also included the following statements: ''I understand that submitting a false, fraudulent, or forged statement or document or omitting a material fact in obtaining licensure may be grounds for disciplinary action against my license'' and ''Under penalty of law, I hereby swear or affirm that the information I have provided in the application is complete and correct, and that I have complied with all criteria for applying on line.'' *Id.* at 6.

[6] Agency records, of which I take official notice, *see* 21 CFR 1316.59(e), show that Applicant also answered ''No'' to Liability Question Two on his January 2012 application. There is, however, no evidence that his response was specifically addressed by the investigating DI at the time.

Respondent consulted with his attorney and decided to withdraw his application. *Id.* at 3. Given that the March 5, 2012 interview involved the same matters as had been discussed at the time Respondent surrendered his registration and that he had been threatened with criminal prosecution, Respondent cannot credibly argue that, at the time he submitted the March 2013 application, he remained confused as to whether he had previously surrendered the registration ''for cause.''

I therefore conclude that substantial evidence supports findings that Respondent materially falsified his application for March 2013 application for registration when he failed to disclose that he had surrendered his DEA registration ''for cause,'' and that he did so intentionally. *See* GX 10, GX 12 at 2–3. I further conclude that these findings support the denial of Respondent's application.

The Public Interest Analysis

The Government also argues that Respondent's application should be denied on the separate ground that his registration is ''inconsistent with the public interest.'' 21 U.S.C. 823(f). More specifically, the Government argues that factors two (experience in dispensing), four (compliance with applicable laws related to controlled substances) and five (other conduct which may threaten public health and safety), support the denial of his application.[7] Government's Request for Final Agency Action, at 10.

With regard to factors two and four, the Government alleges that Respondent issued two controlled-substance prescriptions after he surrendered his registration. In his written statement, Respondent denies any knowledge of both prescriptions, and posits ''that a substitute was given by a nurse without [his] approval because insurance would not cover the non-narcotic prescription that [he] had originally written?'' GX 10, at 2.

Having reviewed the signatures on the prescriptions with the other documents in the record which indisputably contain Respondent's signature (*i.e.,* his written statement of position, the voluntary surrender form, and the DEA Form 222), I conclude that Respondent signed both prescriptions. *See United States* v. *Clifford,* 704 F.2d 86, 90 n.5 (3d Cir. 1983) (''[A] jury can compare a known handwriting sample with another sample to determine if the handwriting in the latter sample is genuine. The jury can make that comparison without the benefit of expert witnesses.'') (citations omitted); *see also* 28 U.S.C. 1731 (''The admitted or proved handwriting of any person shall be admissible, for purposes of comparison, to determine genuineness of other handwriting attributed to such person.'').

Notwithstanding that Respondent did not include a DEA number on the prescription, I find that Respondent unlawfully issued the May 5, 2012 prescription for Lyrica. *See* 21 U.S.C. 841(a)(1) (''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . dispense . . . a controlled substance.''); *id.* § 822(a)(2) (Every person who dispenses . . . shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.''); 21 CFR 1306.03(a)(2) (''A prescription for a controlled substance may be issued only by an individual practitioner who is . . . [e]ither registered or exempted from registration. . . .''); *Cf. id.* § 843(a)(2) (''It shall be unlawful for any person knowing or intentionally . . . to use in the course of the . . . dispensing of a controlled substance . . . a registration number which is fictitious, revoked, suspended, [or] expired. . . .'').

However, I do not find the evidence sufficient to sustain the allegation as to the September 12, 2012 prescription. As the evidence shows, the prescription was originally issued for Bromfed DM (a non-narcotic), but was then changed to Zutripro, a schedule III controlled substance, and bears the handwritten notation ''per Katie Allen.'' The Government offered no further evidence regarding the circumstances surrounding the change in the prescription. It did not explain who Ms. Katie Allen is and where she was working on September 12, 2012. Nor did it offer any evidence that it interviewed the pharmacist who filled the prescription, the patient, or Ms. Allen.

As found above, Respondent also admitted that he pre-signed twenty schedule II order forms and that he mailed them to Whitney, so that Whitney could order controlled substances for his pain clinic and ''start the business,'' which Whitney then used to order oxycodone. Respondent violated federal law and Agency regulations because while he clearly authorized Whitney to order the drugs, he failed to execute a power of attorney for him. *See* 21 U.S.C. 842(a)(5); 21 CFR 1305.04(a); *id.* § 1305.05(a).[8]

Respondent admitted to these violations. GX 10, at 2. However, he then stated that he ''did not know how to order controlled substances'' and that ''that action was pure naiveté and ignorance of the law on my part.'' [9] GX 10, at 2. This is not a particularly persuasive explanation for one who seeks a DEA registration.

I therefore conclude that the evidence with respect to factors two and four supports the conclusion that issuing Respondent a new registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

[7] I acknowledge that Applicant remains licensed in Kentucky, the State in which he seeks registration, and therefore, he meets the CSA's prerequisite for holding a practitioner's registration in that State. See 21 U.S.C. 823(f) (''The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.''); *see also id.* § 802(21) (''The term 'practitioner' means a physician . . . or other persons licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to distribute, dispense, . . . [or] administer . . . a controlled substance.'').

However, the possession of state authority ''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 (9th Cir. 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009). 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). Accordingly, this factor is not dispositive either for, or against, the granting of Respondent's application. *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, there is no evidence that Applicant has been convicted of an offense ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[8] Of further note, Whitney could not have obtained the order forms without Respondent having provided him with his DEA Registration number, which is pre-printed on the forms when issued by DEA. *See* GX 4; *see also* 21 CFR 1305.04(a). However, the Agency has repeatedly held that a registrant is strictly liable for any misconduct engaged in by a person to whom a registrant entrusts his registration. *See Satinder Dang,* 76 FR 51424, 51429 (2011); *Rosemary Jacinta Lewis,* 72 FR 4035, 4041 (2007). The evidence offered by the Government as to whether Whitney and Respondent were diverting controlled substances at CPMG does not, however, create more than a suspicion.

[9] It is well settled that ''ignorance of the law or a mistake of law is no defense.'' *Cheek* v. *United States,* 498 U.S. 192, 199 (1991). Moreover, the principle ''applies whether the law be a statute or a duly promulgated and published regulation.'' *United States* v. *International Minerals & Chemical Corp.,* 402 U.S. 558, 563 (1971).

Factor Five

The Government further argues that Respondent committed actionable misconduct under factor five when he failed to disclose the surrender of his DEA registration on his application to the Ohio Medical Board. Request for Final Agency Action, at 11. In support of its contention, the Government cites *David A. Hoxie, M.D.,* 69 FR 51477, 51478 (2004), for the proposition that providing false answers on a state professional license application ''demonstrate[s] questionable candor.'' *Id.* (citing *Bernard C. Musselman, M.D.,* 64 FR 55965 (1999)). It also cites *Leonard E. Reeves, III,* 63 FR 44471, 44784 (1998), which ordered a stayed revocation of the physician's DEA registration relying, in part, on a state board's denial of the physician's application for a medical license based on the physician's ''total lack of truthful, accurate and complete answers on his written application for licensure.'' [10]

Undoubtedly, providing a materially false answer to a question on a state medical license application is probative evidence of whether a registrant or applicant demonstrates ''questionable candor.'' However, here, in contrast to *Reeves,* there has been no adjudication by the State of Ohio and Respondent retains a valid osteopathic license in that State. Thus, the question remains as to whether this Agency should be adjudicating this allegation in the first instance, especially where, as here, Respondent is neither registered in Ohio nor seeks registration in that State.

To be sure, *Hoxie* went beyond *Reeves* by holding that the physician's falsifications of his medical license applications were actionable under factor five even in the absence of a state board finding. *Hoxie,* however, preceded the Supreme Court's decision in *Gonzales* v. *Oregon,* 546 U.S. 243 (2006). Therein, the Supreme Court explained that the CSA ''manifests no intent to regulate the practice of medicine generally'' and that ''[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers.'' *Id.* at 270.

While the Government contends that Respondent's false statement on his Ohio medical license application can be considered as a separate act of actionable misconduct under factor five, it offers no explanation as to why it is consistent with *Gonzales,* that DEA, rather than the Ohio Medical Board, should be the first body to adjudicate the issue. Nor does the Government offer any explanation as to why the Ohio Board is incapable of enforcing its own laws. Finally, the Government does not even cite the applicable provision of Ohio law, let alone explain whether there is a materiality requirement under Ohio law, and if so, what the standard is under Ohio law.

While the Government's position would be stronger if Respondent was registered in Ohio—on the theory that the falsification of his state application resulted in the State granting him the osteopathic license necessary to obtain his DEA registration,[11] *see* 21 U.S.C. 823(f)—Respondent is neither registered, nor seeking registration, in Ohio. Thus, in the absence of a state board finding, I decline to follow *Hoxie* and do not consider Respondent's falsification of his Ohio application other than for the limited purpose of evaluating his claim that he was confused by the wording on his DEA application.[12]

Summary of the Government's Prima Facie Case

As found above, Respondent intentionally and materially falsified his March 14, 2013 application for a DEA registration. This finding alone provides an adequate basis to deny his application. 21 U.S.C. 824(a)(1) and 843(a)(4)(A).

The evidence also shows that Respondent violated DEA regulations when he provided schedule II order forms to Mr. Whitney, CPMG's owner, and authorized him to order oxycodone without having executed a power of attorney as required by 21 CFR 1305.05(a). Finally, the evidence also shows that Respondent issued a prescription for Lyrica, a schedule V controlled substance, when he was no longer registered, and thus violated 21 U.S.C. 841(a)(1) and 822(a)(2). I therefore find that the Government's evidence under factors two and four is sufficient to conclude that the Government has met its *prima facie* burden on the issue of whether the issuance of a registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

Sanction

Where, as here, the Government has established grounds to deny an application, Respondent must then ''present[] sufficient mitigating evidence'' to show why he can be entrusted with a new registration. *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (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 [an applicant] has committed acts inconsistent with the public interest, the [applicant] must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (citing *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Cuong Tron Tran,* 63 FR 64280, 64283 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995).[13]

While an applicant must accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct in order to establish that its registration is consistent with the public interest, DEA has repeatedly held that these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2010) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009). So too, the Agency can consider the need to deter similar acts, both with respect to the

[10] The physician was not, however, registered in the State which found that he had submitted a false application for a second medical license.

[11] It seems unlikely that a physician would falsify his state medical license application but then truthfully disclose a sanction against his federal registration on his DEA application.

[12] Notably, *Hoxie* does not cite *Reeves,* but rather *Musselman,* as authority for the proposition. *See* 69 FR at 51479. While *Musselman* discusses the factual findings of a state board proceeding which was based, in part, on an allegation that the physician had falsified a state license application, the state board did not find the allegation proved, and in discussing factor five, the Agency's decision discusses only the physician's falsification of his DEA application. *See* 64 FR at 55967. Thus, *Musselman* clearly does not support *Hoxie.*

[13] This rule also applies to other grounds that support the denial of an application, such as where the Government has proven that an applicant materially falsified his application. *See Jackson,* 72 FR, at 23853.

respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

Having reviewed Respondent's Statement of Position, I conclude that he has failed to produce sufficient evidence to show why he should be entrusted with a new registration. His acceptance of responsibility is equivocal at best, as while he appears to acknowledge his wrongdoing with respect to his having provided the Schedule II order forms to Mr. Whitney, his explanation for why he materially falsified his DEA application is clearly disingenuous. So too, is his assertion that he ''did not knowingly tell lies, nor . . . intentionally try to deceive anyone.'' Because Respondent committed intentional misconduct when he materially falsified his application, I find his misconduct to be egregious.[14] Accordingly, his failure to accept responsibility for this misconduct is reason alone to conclude that he cannot be entrusted with a new registration.[15] Moreover, the Agency has a manifest interest in deterring misconduct on the part of others who may contemplate materially falsifying their applications for registration. Accordingly, I conclude that denial of his application is necessary to protect the public interest.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Arthur H. Bell, D.O., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective immediately.

Dated: August 10, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–20353 Filed 8–17–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Alltech Associates, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before October 19, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on April 24, 2015, Alltech Associates, Inc., 2051 Waukegan Road, Deerfield, Illinois 60015 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
4-Methylaminorex (cis isomer) (1590)	I
Gamma Hydroxybutyric Acid (2010)	I
Alpha-ethyltryptamine (7249)	I
Lysergic acid diethylamide (7315)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C–T–7) (7348)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
3,4-Methylenedioxyamphetamine (7400)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-N-N-dimethyltryptamine (7431)	I
Alpha-methyltryptamine (7432)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I

[14] Having found that Respondent's material falsification of his application is egregious and that he has not accepted responsibility for the violation, I need not decide whether the other proven violations are sufficiently egregious to support the denial of the application.

[15] As to the violation in authorizing Whitney to order schedule II drugs, Respondent stated that this was the result of ''pure naiveté and ignorance of the law on my part.'' However, Respondent has offered no evidence of remedial actions he has taken to demonstrate that he is now familiar with the laws and regulations applicable to the lawful dispensing of controlled substances.