

Dated: September 16, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015-24120 Filed 9-22-15; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Euticals, 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 November 23, 2015.

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her 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 July 23, 2015, Euticals, Inc., 2460 W. Bennett Street, Springfield, Missouri 65807-1229 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	Schedule
Gamma Hydroxybutyric Acid (2010)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II

Controlled Substance	Schedule
Phenylacetone (8501)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Oripavine (9330)	II
Tapentadol (9780)	II

The company plans to manufacture the listed controlled substances in bulk for distribution and sale to its customers.

In reference to oripavine (9330), the company plans to acquire the listed controlled substance in bulk from a domestic source in order to manufacture other controlled substances in bulk for distribution to its customers.

Dated: September 16, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15-25]

James Alvin Chaney, M.D.: Decision and Order

On July 23, 2015, Chief Administrative Law Judge (CALJ) John J. Mulrooney, II, issued the attached Recommended Decision (cited as R.D.). Respondent filed Exceptions to the Recommended Decision.

In his Recommended Decision, the CALJ found that on October 21, 2014, the Commonwealth of Kentucky, Board of Medical Licensure, had issued Respondent an Emergency Order of Suspension against his medical license. R.D. at 2. The CALJ further found that on November 17, 2014, the Board issued a final order that affirmed the emergency order of suspension “and that the suspension order remains in effect.” *Id.* Noting that the Controlled Substances Act defines “term ‘practitioner’ [to] mean[] a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to . . . dispense [or] administer . . . a controlled substance in the course of professional practice,” *id.* at 3 (quoting 21 U.S.C. 802(21)), as well as that the registration provision applicable to practitioners directs the Attorney General to “register [a] practitioner[] . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices,” *id.* (quoting 21 U.S.C. 823(f)), the CALJ then noted that the Agency “has long held that possession of authority under state law

to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration.” *Id.* (collecting cases). Because there is no dispute that “Respondent lacks state authority to handle controlled substances in” Kentucky, the CALJ granted the Government’s motion for summary disposition and recommended that Respondent’s registration be revoked.¹ *Id.* at 5.

In his Exceptions, Respondent argues that Board’s Emergency Order suspending his license “is not a final order as it has been appealed and is currently being reviewed by the Kentucky Court of Appeals.” Exceptions at 1. He argues that the CALJ’s Recommended Decision is therefore “based upon an order that is not final and consequently will constitute arbitrary and capricious action.” *Id.* at 2. Finally, Respondent contends that “[s]ummary judgment is improper because issues of fact exist concerning the enforceability of the temporary suspension of [his] medical license given its unconstitutionality.” *Id.*

I reject Respondent’s contentions. Putting aside whether—in light of the state Hearing Officer’s issuance of the “Final Order Affirming The Emergency Order of Suspension”—Respondent has accurately described the procedural posture of the state licensing matter, based on the plain language of sections 802(21) and 823(f), this Agency has held repeatedly that “the controlling question” in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a DEA registration “is currently authorized to handle controlled substances in the [S]tate.” *James L. Hooper*, 76 FR 71371, 71371 (2011) (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), *pet. for rev.*

¹ While the Government alleged in the Order to Show Cause that Respondent’s registration does not expire until August 31, 2016, Show Cause Order, at 1; and in his hearing request, Respondent states that he “holds a medical license . . . and a DEA registration,” Hearing Request, at 1; the Agency is still required to establish that it has jurisdiction to act. *See Sharad C. Patel*, 80 FR 28693, 28694 n.3 (2015) (“Even in summary disposition proceedings which are based on a lack of state authority, the ALJ is obligated to make a finding establishing that the Agency has jurisdiction.”); *see also* 5 U.S.C. 706(2)(C) (directing reviewing courts “to hold unlawful and set aside agency action, findings and conclusions found to be . . . in excess of statutory jurisdiction”). This generally requires the ALJ to make a finding either that a respondent retains an active registration or has submitted an application for registration.

In the interest of conducting an expeditious review of this matter, I have taken official notice of Respondent’s registration record with the Agency and find that his registration does not expire until August 31, 2016. *See* 5 U.S.C. 556(e); 21 CFR 1316.59(e). However, in the future, where a recommended decision lacks the requisite finding, I will remand the matter for this purpose.

denied, *Hooper v. Holder*, 481 Fed.Appx. 826 (4th Cir. 2012). Thus, it is of no consequence that the State has employed summary process in suspending Respondent's state license and that the Board's "order remains subject to challenge in either [further] administrative or judicial proceedings." *Patel*, 80 FR at 28694; see also *Gary Alfred Shearer*, 78 FR 19009, 19012 (2013); *Michael G. Dolin*, 65 FR at 5661, 5662 (2000).

As for Respondent's contention that summary disposition is inappropriate "because issues of fact exist concerning the enforceability of the temporary suspension" order, the only fact that is material in this proceeding is whether Respondent "is currently authorized to handle controlled substances" by the State. *Hooper*, 76 FR at 71371; cf. *Sunil Bhasin*, 72 FR 5082, 5083 (2007) (holding that a registrant cannot collaterally attack the results of a state administrative or criminal proceeding in a proceeding brought under section 304 (21 U.S.C. 824(a)). Accordingly, because the suspension order remains in effect, I adopt the Recommended Decision² and will order that Respondent's registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 28 CFR 0.100(b), I order that DEA Certificate of Registration BC3278492 issued to James Alvin Chaney, M.D., be, and it hereby is, revoked. I further order that any application of James Alvin Chaney, M.D., to renew or modify his registration be, and it hereby is, denied. This Order is effective immediately.³

Dated: September 15, 2015.

Chuck Rosenberg,

Acting Administrator.

Brian Bayly, Esq., for the Government.

Lisa English Hinkle, Esq., for the Respondent.

²Notwithstanding that the language of section 824(a) authorizes either the suspension or revocation of a registration upon the making of one of the five findings enumerated therein, see R.D. at 4 n.1, the Agency has consistently interpreted the CSA as mandating revocation where a practitioner's state authority has been suspended or revoked. As the Fourth Circuit has held, "[b]ecause sections 823(f) and 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the [Administrator's] decision to construe section 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA." *Hooper*, 481 Fed.Appx. at 828.

³For the same reasons that lead the Board to order the emergency suspension of Respondent's medical license (*i.e.*, his indictment on various counts of the unlawful distribution of controlled substances), I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION AND RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Chief Administrative Law Judge John J. Mulrooney, II. The Deputy Assistant Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause (OSC) dated May 21, 2015, seeking to revoke the DEA Certificate of Registration (COR), Number BC3278492, of James Alvin Chaney, M.D. (Respondent), pursuant to 21 U.S.C. 824(a)(3) and 21 U.S.C. 823(f), and deny any pending applications for renewal or modification of the COR, pursuant to 21 U.S.C. 823(f). In the OSC, the Government alleges that the Respondent is, *inter alia*, without "authority to handle controlled substances in the Commonwealth of Kentucky" as grounds for revocation of the Respondent's DEA registration. On July 2, 2015, the Respondent, by counsel, filed a Request for Hearing in the above-captioned matter. The Request for Hearing stated that a hearing is appropriate because "the review of [the Kentucky Board of Medical Licensure's] illegal suspension by emergency order of [the Respondent's] medical license is currently on appeal before the Kentucky Court of Appeals . . ." and because "any action concerning [the Respondent's DEA COR] . . . is premature . . ." Req. for Hrg. at 7.

Consistent with my direction, the parties have briefed the issues. On July 9, 2015, the Government filed a Motion for Summary Disposition Based on Respondent's Lack of State Authorization to Handle Controlled Substances and Submission of Evidence in Support of Such Motion (Motion for Summary Disposition), seeking that this tribunal issue a Recommended Decision granting the Government's Motion on the ground that the Respondent is currently without state authority to handle controlled substances. Mot. for Summary Disp. at 1. According to the Government's Motion, the Commonwealth of Kentucky, Board of Medical Licensure (BML) suspended the Respondent's license to practice medicine effective October 21, 2014, and that suspension order remains in effect. *Id.* Attached to the Government's Motion is the BML Emergency Order of Suspension dated October 21, 2014 suspending the Respondent's state license No. 28914 on the grounds that there was probable cause to believe that the Respondent's practice constituted a

danger to the health, welfare, and safety of his patients or the general public, as evidenced by the Respondent's indictments for crimes related to controlled substances. *Id.* at 1–2; Attachment 1 at 1–4. Also attached to the Government's Motion is the BML Final Order Affirming the Emergency Order of Suspension, dated November 17, 2014. Attachment 2 at 17.

On July 23, the Respondent, through counsel, filed a reply styled "Response to Government's Motion for Summary Judgment" (Respondent's Reply). In his Reply, the Respondent alleges that his situation is distinguishable from Agency precedent mandating revocation for lack of state authority, Resp't Reply at 4–5, because the BML's suspension of his license was "based on the [BML's] application of an incorrect rule of law and an unconstitutional regulation." *Id.* at 5. In opposing the Government's requested relief, the Respondent also avers that inasmuch as he is not currently practicing medicine or prescribing controlled substances, maintenance of his DEA COR constitutes no danger to the public, and that he "should not be penalized" by the DEA because his underlying federal criminal charges have not yet been resolved. *Id.* at 8.

In order to revoke a registrant's DEA registration, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e) (2015). Once the DEA has made its *prima facie* case for revocation of the registrant's DEA COR, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall v. DEA*, 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys v. DEA*, 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. U.S. Dept. of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston*, 45 FR 72311 (1980).

The Controlled Substances Act (CSA) requires that, in order to maintain a DEA registration, a practitioner must be authorized to handle controlled substances in "the jurisdiction in which he practices." See 21 U.S.C. 802(21) (2012) ("[t]he term 'practitioner' means a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice"); see also 21 U.S.C. 823(f) (2012) ("The Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State

in which he practices.”). DEA has long held that possession of authority under state law to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration. *Serenity Café*, 77 FR 35027, 35028 (2012); *David W. Wang*, 72 FR 54297, 54298 (2007); *Sheran Arden Yeates*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993); *Bobby Watts, M.D.*, 53 FR 11919 (1988). Because “possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,” this Agency has consistently held that “the CSA requires the revocation of a registration issued to a practitioner who lacks [such authority].” *Roy Chi Lung, M.D.*, 74 FR 20346, 20347 (2009); see also *Scott Sandarg, D.M.D.*, 74 FR 17528, 174529 (2009); *John B. Freitas, D.O.*, 74 FR 17524, 17525 (2009); *Roger A. Rodriguez, M.D.*, 70 FR 33206, 33207 (2005); *Stephen J. Graham, M.D.*, 69 FR 11661 (2004); *Abraham A. Chaplan, M.D.*, 57 FR 55280 (1992); see also *Harrell E. Robinson, M.D.*, 74 FR 61370, 61375 (2009).¹ “[R]evocation is warranted even where a practitioner’s state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State’s action at which he may ultimately prevail.” *Kamal Tiwari, M.D.*, 76 FR 71604, 71606, (2011); see also *Bourne Pharmacy, Inc.*, 72 FR 18273, 18274 (2007); *Anne Lazar Thorn, M.D.*, 62 FR 12847 (1997). Additionally, Agency precedent has established that the existence of other proceedings in which the Respondent is involved is not a basis upon which to justify a stay of DEA administrative enforcement proceedings. *Grider Drug #1 & Grider Drug #2*, 77 FR 44069, 44104 n.97 (2012).

Congress does not intend for administrative agencies to perform meaningless tasks. See *Philip E. Kirk, M.D.*, 48 FR 32887 (1983), *aff’d sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984); see also *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 605 (1st Cir. 1994); *NLRB v.*

Int’l Assoc. of Bridge, Structural & Ornamental Ironworkers, AFL-CIO, 549 F.2d 634 (9th Cir. 1977); *United States v. Consol. Mines & Smelting Co.*, 455 F.2d 432, 453 (9th Cir. 1971). Thus, it is well-settled that, where no genuine question of fact is involved or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required. See *Jesus R. Juarez, M.D.*, 62 FR 14945 (1997); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993). Here, the supplied BML Order establishes, and the Respondent does not contest, that the Respondent is currently without authorization to handle controlled substances in Kentucky, the jurisdiction where the Respondent holds the DEA COR that is the subject of this litigation.

Summary disposition of an administrative case is warranted where, as here, “there is no factual dispute of substance.” See *Veg-Mix, Inc.*, 832 F.2d 601, 607 (D.C. Cir. 1987) (“an agency may ordinarily dispense with a hearing when no genuine dispute exists”).² While not unsympathetic to the procedural issues raised by the Respondent in his state administrative proceedings, under current Agency precedent, the disposition of the Government’s motion is wholly dependent upon a single issue: whether he continues to possess authority under state law to handle controlled substances—which he does not.

At this juncture, no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances in the state of Kentucky. Because the Respondent lacks such state authority, both the plain language of applicable federal statutory provisions and Agency interpretive precedent dictate that he is not entitled to maintain his DEA registration. Simply put, there is no contested factual matter adducible at a hearing that would provide DEA with the authority to allow the Respondent to continue to hold his COR.

Accordingly, I hereby

GRANT the Government’s Motion for Summary Disposition; and further

RECOMMEND that the Respondent’s DEA registration be REVOKED

² Even assuming, *arguendo*, the possibility that the Respondent’s state controlled substances privileges could be reinstated, summary disposition would still be warranted because under Agency precedent “revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement.” *Rodriguez*, 70 FR 33207 (citations omitted), and even where there is a judicial challenge to the state medical board action actively pending in the state courts. *Michael G. Dolin, M.D.*, 65 FR 5661, 5662 (2000).

forthwith³ and any pending applications for renewal be DENIED. Dated: July 23, 2015. John J. Mulrooney II, Chief Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–23]

Brown’s Discount Apothecary, BC, Inc., and Bolling Apothecary, Inc.

On May 18, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Brown’s Discount Apothecary, BC, Inc. (holder of DEA Certificate of Registration FB3717153), of Jasper, Alabama and Bolling Apothecary, Inc., (holder of DEA Certificate of Registration AB9375456), of Fayette, Alabama. Show Cause Order, at 1. The Show Cause Order proposed the revocation of each pharmacy’s DEA Certificate of Registration, on the ground that on April 7, 2015, the Alabama State Board of Pharmacy issued an Emergency Suspension Order suspending each pharmacy’s Alabama Controlled Substances Permit, and that therefore, each pharmacy is “without authority to handle controlled substances in Alabama, the [S]tate in which each is registered with the DEA.” *Id.* at 1–2.

On May 20, 2015, a Diversion Investigator from the Birmingham District Office personally served the Order to Show Cause on Bolling Apothecary, Inc. Notice of Service of Order to Show Cause, at 1. According to the Government, on June 2, 2015, an attorney “accepted service by email of the Order to Show Cause on behalf of Brown’s Discount Apothecary and its owner George Bolling, Jr. *Id.*

On June 1, 2015, George R. Bolling, Sr., owner of Respondent Bolling Apothecary, Inc., filed a request for a hearing on behalf of the pharmacy with the Office of Administrative Law Judges

³ While Agency precedent has held that a stay of DEA administrative proceedings is unlikely ever to be justified by the existence of ancillary proceedings (*Grider Drug #1 & Grider Drug, #2*, 77 FR 44069, 44104 n.97 (2012)), the Agency recently held revocation proceedings in abeyance at the post-hearing adjudication level for a lengthy period pending the resolution of criminal fraud charges and “pending resolution of [a state] Board proceeding.” *Odette L. Campbell, M.D.*, 80 FR 41062, 41064 (2015). However, inasmuch as no stay was sought by the Respondent here, and good cause does not appear to exist in any event, the Government’s motion will be granted and the case forwarded for a final order.

¹ But see 21 U.S.C. 824(a)(3) (2012) (“A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority . . .”) (emphasis added). Thus, notwithstanding the Agency’s extensive body of internal precedent to the contrary, the plain language of section 824(a)(3) provides that loss of state authority constitutes a discretionary—not mandatory—basis for revocation. However, inasmuch as the Agency precedent is clear on the matter, I am without authority or inclination to render a contrary interpretation.