

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.