

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 Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on September 13, 2018, Janssen Pharmaceuticals Inc., 1440 Olympic Drive, Bldgs. 1–5 & 7–14, Athens, Georgia 30601–1645, applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Poppy Straw Concentrate	9670	II
Tapentadol	9780	II

The company plans to import an intermediate form of tapentadol (9780) to bulk manufacture tapentadol for distribution to its customers. The company plans to import thebaine (9333) derivatives as reference standards. The company plans to import concentrated poppy straw (9670) to bulk manufacture other controlled substances. No other activity for these drug codes is authorized for this registration.

Dated: November 6, 2018.

John J. Martin,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Edward A. Ridgill, M.D.; Decision and Order

On May 15, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Edward A. Ridgill, M.D., (Applicant), of Whittier, California. The Show Cause Order proposed the denial of Applicant’s application for a DEA Certificate of Registration, “Application Number W15031876C,” as a practitioner on the

grounds that Applicant “ha[s] been convicted of a felony relating to controlled substances” and because granting Respondent a “registration would be inconsistent with the public interest.” Appendix (App.) 1 to Government’s Request for Final Agency Action (RFAA), at 1 (citing 21 U.S.C. 823(f), 824(a)(2), (a)(4)).

With respect to the Agency’s jurisdiction, the Show Cause Order alleged that on May 4, 2015, Applicant submitted an application for a DEA registration “to handle controlled substances in Schedules II–IV, with Application Number W15031876C, at 4130 Eadhill Place, Whittier, CA.” *Id.* at 2.¹

As to the substantive grounds for the proceeding, the Show Cause Order alleged that “[o]n or about December 4, 2017, a jury convicted” Applicant of 26 counts of unlawful distribution of controlled substances (specifically, hydrocodone, alprazolam, and carisoprodol) in violation of 21 U.S.C. 841(a)(1) and 18 U.S.C. 2 and that the “[j]udgment was entered on April 23, 2018.” *Id.* The Order asserted that Respondent’s “[c]onviction of a felony relating to controlled substances warrants denial of [his] application for registration.” *Id.* (citing 21 U.S.C. 824(a)(2)). The Order also asserted that granting Respondent’s application would be “inconsistent with the public interest” in light of his felony convictions. *Id.* (citing 21 U.S.C. 823(f), 824(a)(4)).

The Show Cause Order notified Applicant of (1) his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing either option, and (3) the consequence for failing to elect either option. *Id.* at 2–3. (citing 21 CFR 1301.43). The Order also notified Applicant of his right to submit a corrective action plan. *Id.* at 3–4 (citing 21 U.S.C. 824(c)(2)(C)).

With respect to service, a Diversion Investigator (DI) with DEA’s Los Angeles Field Division executed a Declaration on September 19, 2018 stating that she “learned that following his conviction, [Applicant] was incarcerated at Victorville Federal Prison . . . in Adelanto, CA.” App. 4 (Declaration of DI) to RFAA, at 2. As a

¹ The Show Cause Order also alleged that Applicant was previously “registered with the DEA as a practitioner authorized to handle controlled substances in Schedules II–V” under DEA Certificate of Registration No. FR3094997 at 3625 E. Martin Luther King Boulevard, Suite 9, Lynwood, California. *Id.* at 1. The Order alleged that Applicant “voluntarily surrendered” this registration on March 12, 2015 “during [his] arrest for conspiracy to distribute controlled substances.” *Id.*

result, the DI stated in her Declaration that she mailed a copy of the Show Cause Order by certified mail and addressed it to Applicant at the Victorville United States Penitentiary in Adelanto, California. *Id.*² In her Declaration, the DI attached and authenticated a return receipt from the U.S. Postal Service confirming that the mailing was so addressed and was delivered to that penitentiary on June 15, 2018. *Id.*; see Attachment A to App. 4. I therefore find that the Government accomplished service on June 15, 2018. See *Warren B. Dailey, M.D.*, 82 FR 46525, 46526 (2017) (holding that sending Show Cause Order to Respondent by certified mail at U.S. penitentiary and with proof of return receipt was sufficient to establish that Government lawfully accomplished service).

On October 3, 2018, the Government forwarded its Request for Final Agency Action and evidentiary record to my Office. In its Request, the Government represents that more than 30 days had passed since Applicant had been served and that “DEA had not received a request for hearing or any other reply” from him during that time. RFAA, at 3. Based on the Government’s representation and the record, I find that more than 30 days have passed since the Order to Show Cause was served on the Applicant, and he has neither requested a hearing nor submitted a written statement in lieu of a hearing. See 21 CFR 1301.43(d). Accordingly, I find that Applicant has waived his right to a hearing or to submit a written statement and issue this Decision and Order based on relevant evidence submitted by the Government. See *id.* I make the following findings.

² The DI also stated in her Declaration that the Show Cause Order “was emailed to [Applicant’s] criminal defense attorney” by a Task Force Officer “on or about June 11, 2018.” *Id.* However, this attempt at service of the Order pursuant to 21 U.S.C. 824(c), standing alone, would be insufficient for at least two reasons. First, the Government failed to establish that the attorney had “the power to accept service” on behalf of the Applicant in this proceeding. *Warren B. Dailey, M.D.*, 82 FR 46525, 46526 (2017) (internal citations and quotations omitted). Second, assuming the attorney had such authority, the record does not contain (1) a statement that explains whether the DI had independent personal knowledge of the email, (2) a declaration from the Task Force Officer or another declarant who has personal knowledge of the email, or (3) any other evidence corroborating the DI’s statement that the Task Force Officer had emailed the attorney. Cf. *Richard Hauser, M.D.*, 83 FR 26308, 26309 n.5 (2018) (finding that a DI’s declaration that he “verified” a document’s authenticity by conferring with another DI was insufficient absent a declaration from a DI with personal knowledge of the document’s authenticity or other evidence to corroborate its authenticity).

Findings of Fact

On or about May 1, 2015, Applicant applied for a practitioner's registration seeking authority to dispense controlled substances in schedules II through IV at the proposed address of 4130 Eadhill Place, Whittier, California. App. 2 (Certification of Registration History) to RFAA, at 1.³ DEA assigned "control number W15031876C" to the application. *Id.* The application is in a "new pending status" with DEA. *Id.*

On September 6, 2016, a federal grand jury returned an indictment against Applicant charging him with (1) seven counts of unlawful prescribing and distribution of hydrocodone when it was a schedule III controlled substance, in violation of 21 U.S.C. 841(a)(1), (b)(1)(E) and 18 U.S.C. 2(b); (2) six counts of unlawful prescribing and distribution of hydrocodone when it was a schedule II controlled substance, in violation of 21 U.S.C. 841(a)(1), (b)(1)(C) and 18 U.S.C. 2(b); (3) nine counts of unlawful prescribing and distribution of alprazolam, a schedule IV controlled substance, in violation of 21 U.S.C. 841(a)(1), (b)(2) and 18 U.S.C. 2(b); and (4) four counts of unlawful prescribing and distribution of carisoprodol, a schedule IV controlled substance, in violation of 21 U.S.C. 841(a)(1), (b)(2) and 18 U.S.C. 2(b). App. 3 to RFAA, at 1–5. On December 4, 2017, a federal jury found Applicant guilty on all counts. *Id.* at 8. On April 23, 2018, a federal district judge in the U.S. District Court for the Central District of California entered a Judgment and Probation/Commitment Order, Case No. CR16–0631 (C.D. Cal.), sentencing Applicant to a term of imprisonment "of 60 months on each of Counts 1 to 26 of the Indictment, to be served concurrently." *Id.* at 9. Thus, I find that Respondent has been convicted of felony offenses under the Controlled Substances Act (CSA) "relating to [] substance[s] defined in [the CSA] as a controlled substance." 21 U.S.C. 824(a)(2); *see also id.*, § 841(a)(1), (b)(1)–(2) (prescribing for various felony sentences of more than one year).

³ Although the Government states in its Request that Applicant submitted his DEA application "[o]n or about May 4, 2015," RFAA, at 2, the Government attached to its Request a Certification of Registration History, which was sworn to and certified on September 27, 2018 by DEA's Associate Chief of Registration and Program Support Section, stating that Applicant submitted his DEA "online application . . . on/about May 1, 2015." App. 2, at 1. In addition, the certification included a copy of the online application which states: "Submission Date: 05–01–2015." *Id.* at 3. Thus, I find that Applicant submitted his DEA application on or about May 1, 2015.

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, it is well established that I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *see also Kevin Dennis, M.D.*, 78 FR 52787, 52974 (2013); *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011).

Furthermore, under Section 304(a) of the CSA, a registration may be revoked or suspended "upon a finding that the registrant . . . has been convicted of a felony under this subchapter . . . or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance." 21 U.S.C. 824(a)(2). *See John P. Moore, III, M.D.*, 82 FR 10398, 10401 (2017) (revocation warranted for conviction of felony offense); *Algirdas J. Krisciunas, M.D.*, 76 FR 4940, 4944 (2011) (revocation warranted for conviction of felony offense under CSA); *Hung Thien Ly, M.D.*, 75 FR 49955, 49956 (2010) (same). Under the same section of the CSA, a registration may also be revoked or suspended if the registrant "has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4).

"DEA has long held 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." *Richard D. Vitalis, D.O.*, 79 FR 68701, 68708 (2014) (citing *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 Applicant was convicted of a felony relating to a controlled substance under the CSA is properly considered in this proceeding. *Thomas G. Easter II, M.D.*, 69 FR 5579, 5580 (2004) (denial of application because applicant was "convicted of eight State felonies relating the distribution or dispensing of controlled substances . . . is independently appropriate under 21 U.S.C. 823(f) and 824(a)(2)"); *Brady Kortland Fleming*, 46 FR 45841, 45842 (1981) (finding that respondent's conviction of a felony offense related to controlled substances that would justify revocation under 21 U.S.C. 824(a)(2) also provides a statutory basis for denial of respondent's registration under 21 U.S.C. 823(f)); *see also Samuel S. Jackson*, 72 FR 23848, 23852 (2007). The Government bears the burden of proof in showing that the issuance of a registration is inconsistent with the public interest. 21 CFR 1301.44(d). I conclude that there are two separate and independent grounds to deny Applicant's application.

First, as found above, a federal district judge in the United States District Court for the Central District of California entered a judgment convicting Applicant of 26 counts of unlawful distribution of controlled substances under the CSA (hydrocodone, alprazolam, and carisoprodol) in violation of 21 U.S.C. 841(a)(1). Each count of conviction was for a felony offense under the CSA. *See* App. 3 to RFAA, at 9 (citing 21 U.S.C. 841(a)(1), (b)(1)(C) ("[i]n the case of a controlled substance in schedule I or II . . . such person shall be sentenced to a term of imprisonment of not more than 20 years"), (b)(1)(E) ("in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 years"), (b)(2) ("[i]n the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 5 years")). Thus, I find that Applicant "has been convicted of a felony offense . . . relating to any substance defined in [the CSA] as a controlled substance." 21 U.S.C. 824(a)(2). This finding alone provides reason to deny Applicant's application for a DEA Certificate of Registration.

Second, Applicant's aforementioned conviction is both relevant and adverse

to Applicant regarding factors three and four of the public interest determination. *Easter*, 69 FR at 5581 (finding that felony convictions related to distribution of controlled substances “are relevant and adverse to” applicant regarding public interest factors two, three, four, and five). Specifically, I may deny Applicant’s pending application pursuant to factor three (21 U.S.C. 823(f)(3)) alone because he has been convicted for unlawful distribution of controlled substances under the CSA. *Trenton F. Horst, D.O.*, 80 FR 41079, 41090 (2015) (holding that pursuant to 21 U.S.C. 823(f)(3), DEA “may deny a pending application for a certificate of registration upon a finding that the applicant has been convicted of a felony related to controlled substances under state or federal law”). In the same vein, Applicant’s conviction for violating the CSA also reflects his lack of “[c]ompliance with applicable . . . Federal . . . laws relating to controlled substances” under factor four. 21 U.S.C. 823(f)(4). Accordingly, I find that the Government’s evidence of Applicant’s convictions is adverse to Applicant with respect to public interest factors three and four and thus establishes that granting Applicant’s application “would be inconsistent with the public interest.” 21 U.S.C. 823(f); *Arvinder Singh, M.D.*, 81 FR 8247–48 & n.2 (2016) (affirming ALJ’s finding that respondent’s felony convictions in violation of the CSA implicated multiple public interest factors (including factors three and four) and thus warranted denial of his application as inconsistent with the public interest).

For all these reasons, and because Applicant failed to respond to the Show Cause Order and thus has failed to offer any evidence to the contrary, I will order that his application be denied.

Order

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

Dated: October 31, 2018.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2018–25224 Filed 11–19–18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Organix, 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 on or before January 22, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette 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 re delegated to the Assistant Administrator of the DEA Diversion Control Division (“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 September 26, 2018, Organix Inc., 240 Salem Street, Woburn, Massachusetts 01801–2029, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substances	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Lysergic acid diethylamide ..	7315	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
Heroin	9200	II
Morphine	9300	II

The company plans to synthesize the above-listed controlled substances for distribution to its research and forensics customers.

Dated: November 2, 2018.

John J. Martin,

Assistant Administrator.

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BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Lipomed

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 on or before December 20, 2018. Such persons may also file a written request for a hearing on the application on or before December 20, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007).

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 re delegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.