

agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (5) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Part 732 establishes the procedures and criteria for approval and disapproval of State program submissions. The information is used to evaluate whether State regulatory authorities are meeting the provisions of their approved programs.

Title of Collection: Procedures and Criteria for Approval or Disapproval of State Program Submissions.

OMB Control Number: 1029-0024.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and tribal regulatory authorities.

Total Estimated Number of Annual Respondents: 33.

Total Estimated Number of Annual Responses: 33.

Estimated Completion Time per Response: Varies from 5 hours to 350 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 4,765.

Respondent's Obligation: Retain a Benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

*Information Collection Clearance Officer,
Division of Regulatory Support.*

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-593]

Bulk Manufacturer of Controlled Substances Application: Scottsdale Research Institute

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 April 24, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on October 31, 2019, Scottsdale Research Institute, 5436 E Tapekim Road, Cave Creek, Arizona 85331 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to bulk manufacture the above controlled substances to provide consistent medical grade active pharmaceutical ingredient (API) and reference standards for distribution to their research customers.

Dated: January 31, 2020.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020-03611 Filed 2-21-20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jaime C. David, M.D.; Decision and Order

On September 26, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Jaime C. David, M.D. (hereinafter, Registrant) of Apple Valley, California. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BD9798818. *Id.* It alleged that Registrant is without "authority to handle controlled substances in the State of California, the state in which [Registrant is] registered with the DEA." *Id.* (citing 21 U.S.C. 823(f) and 824(a)(3)).

Specifically, the OSC alleged that the Medical Board of California (hereinafter, Board) issued an Order on August 24, 2016 revoking Registrant's medical license effective September 23, 2016, and that such Order remains in effect. *Id.* The OSC further alleged that because the Board revoked Registrant's medical license, Registrant lacks the authority to handle controlled substances in the State of California. *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated April 13, 2018, a Diversion Investigator (hereinafter, DI) assigned to the Riverside Resident Office of the Los Angeles Field Division in Riverside, California, detailed her attempts to serve the OSC to Registrant. Request for Final Agency Action (hereinafter, RFAA) Ex. 3. The DI stated that she attempted to serve Registrant in person at his last known residence, 41145 Ridgegate Lane, Palmdale, California 93551 (hereinafter, the residence). *Id.* at 2. The DI obtained this address from a report written by the

prior Diversion Investigator that reflected that the address was listed on the Medical Board of California's online profile of Registrant and was previously used by DEA to send correspondence to him. *Id.* At the residence, the DI stated that a man answered the door and told her that "he was [Registrant's] nephew and that [Registrant] had returned to the Philippines with no intention of returning to the United States." *Id.* The man declined to accept a copy of the OSC but said he would inform Registrant that the DEA had been to the residence. *Id.*

On September 28, 2017, the DI attempted to send notification of the OSC to Registrant via email using the email address that the DEA had on file, but "[t]he delivery of the email that [she] sent was returned 'failed.'" *Id.* On October 26, 2017, the DI sent copies of the OSC by first class mail and certified mail to (1) Registrant's residence, and (2) his DEA registered location of 18419 Highway 18, Suite 6, Apple Valley, California 92307. *Id.* The DI stated that neither of the letters sent by first class mail were returned to the DEA, but that the certified letters sent to the Registrant's residence and registered location were returned as "refused" and "vacant," respectively. *Id.*

The Government forwarded its RFAA, along with the evidentiary record, to this office on April 18, 2018. In its RFAA, the Government contends that it made all reasonable actions to serve Registrant—attempting to serve him by email, in-person, and by mail—and that actual service on Registrant is not required. RFAA, at 3–4. The Government requests a final order revoking Registrant's DEA Certificate of Registration because Registrant "lacks state authority to handle controlled substance in the State of California, the state where [Registrant] is registered." *Id.* at 1.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government's attempts to serve Registrant were legally sufficient. Due process does not require actual notice. *Jones v. Flowers*, 547 U.S. 220, 226 (2006). "[I]t requires only that the Government's effort be reasonably calculated to apprise a party of the pendency of the action." *Dusenbery v. United States*, 534 U.S. 161, 170 (2002) (internal quotations omitted). Here, the Government mailed the OSC by first-class mail and certified mail to Registrant's address of record and last-known residence, emailed the OSC to the email address that Registrant had provided to the Government, and visited Registrant's last-known residence where

an occupant of the residence who purported to be Registrant's nephew declined to accept the OSC and said that Registrant had left the United States. RFAA Ex. 3. "[T]he Due Process Clause does not require . . . heroic efforts by the Government" to find Registrant. *Id.* I find, therefore, that under the circumstances, the Government's efforts to notify Registrant of the OSC were reasonable and satisfied due process.

I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BD9798818 at the registered address of 18419 Highway 18, Suite 6, Apple Valley, California 92307. RFAA Ex. 1. Pursuant to this registration, Registrant was authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expired on June 30, 2018. *Id.*¹

The Status of Registrant's State License

On August 24, 2016, the Medical Board of California issued a Decision After Non-Adoption and Order ("Order"). RFAA Ex. 3, Attach. A. According to the Order, Registrant prescribed a controlled substance to himself, "used dangerous drugs to an extent or in a manner dangerous or injurious to himself, to another person, or to the public," "used dangerous drugs to an extent that his use impairs his ability to practice medicine safely," and "engaged in unprofessional conduct." *Id.* at 15–16. The Order further stated that Registrant's "ability to practice medicine safely is impaired

due to mental illness affecting his competence as a result of his heavy use of controlled substances and dangerous drugs." *Id.* at 16. The Order concluded that as a result of Registrant's "multiple, serious violations and absence of rehabilitation, the public health, safety, and welfare [could not] be protected by any discipline short of revocation" and revoked Registrant's license to practice medicine effective September 23, 2016. *Id.* at 17. The Medical Board of California's online records, of which I take official notice, document that Registrant's license is still revoked.² Medical Board of California License Verification, https://www.mbc.ca.gov/Breeze/License_Verification.aspx (last visited Jan. 31, 2020).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in California, the state in which Registrant is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.*, 76 FR 71,371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick*

² Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (dea.addo.attorneys@dea.usdoj.gov) or by mail to Office of the Administrator, Attn: ADDO, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152.

¹ The fact that a Registrant allows his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68,474 (2019).

Marsh Blanton, M.D., 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a physician . . . or other person 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.” 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner’s registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617.

According to California statute, “[n]o person other than a physician . . . shall write or issue a prescription.” Cal. Health & Safety Code § 11150 (Westlaw 2019). Further, “physician,” as defined by California statute, is a person who is “licensed to practice” in California. *Id.* § 11024.

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant’s DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BD9798818 issued to Jaime C. David, M.D. This Order is effective March 25, 2020.

Dated: January 31, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–03626 Filed 2–21–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–584]

Bulk Manufacturer of Controlled Substances Application: Synthcon, LLC

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 April 24, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 9, 2019, Synthcon, LLC, 770 Wooten Road, Suite 101, Colorado Springs, Colorado 80915–3538 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Methamphetamine	1105	II
3-Fluoro-N-methylcathinone (3-FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4-FMC)	1238	I
Pentedrone (α-methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
4-Methyl-N-ethylcathinone (4-MEC)	1249	I
Naphyrone	1258	I
N-Ethylamphetamine	1475	I
N,N-Dimethylamphetamine	1480	I
Aminorex	1585	I
4-Methylaminorex (cis isomer)	1590	I
Gamma Hydroxybutyric Acid	2010	I
Methaqualone	2565	I
Mecloqualone	2572	I
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I
Alpha-ethyltryptamine	7249	I
l-bogaine	7260	I
CP-47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol]	7297	I
CP-47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol]	7298	I
Lysergic acid diethylamide	7315	I
2,5-Dimethoxy-4-(n-propylthiophenethylamine (2C-T-7)	7348	I
Tetrahydrocannabinols	7370	I
Mescaline	7381	I
2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine (2C-T-2)	7385	I