by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

As for South Carolina state law, grounds for disciplinary action against a physician include when the physician has: ''engaged in dishonorable, unethical, or unprofessional conduct that is likely either to deceive, defraud, or harm the public''; ''violated the code of medical ethics adopted by the [State Board of Medical Examiners] or has been found by the [State Board of Medical Examiners] to lack the ethical or professional competence to practice''; ''failed to prepare or maintain an adequate patient record of care provided''; ''engaged in behavior that exploits the physician-patient relationship in a sexual way''; and ''improperly managed medical records, including failure to maintain timely, legible, accurate, and complete medical records.'' S.C. Code Ann. § 40–47–110.

Further, South Carolina regulations require that prior to prescribing to a patient, a physician must establish a proper physician-patient relationship, which entails that the physician ''make an informed medical judgment based on the circumstances of the situation and on the [physician's] training and experience''; ''personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan''; ''discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options''; and ''ensure the availability of the [physician] or coverage for the patient for appropriate follow-up care.'' *Id.* § 40–47–113(A).[6]

Here, consistent with Registrant's admissions, the Agency finds that Registrant repeatedly issued prescriptions for controlled substances without conducting an appropriate evaluation, without making a proper diagnosis, without providing a therapeutic plan, and without discussing the risks, benefits and treatment options with his patients. RFAAX 1, at 3–5. Registrant has also admitted and the Agency finds that Registrant: engaged in sexual conduct with a patient prior to issuing the patient prescriptions for controlled substances; issued a cocktail prescription of opioids and a benzodiazepine to multiple patients on multiple occasions while failing to document his reasoning for so doing; and increased the dosages of controlled substance prescriptions for multiple patients without medical justification for so doing. *Id.* Based on Registrant's numerous deviations from the standard of care, DEA's medical expert concluded, and the Agency finds, that these prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *Id.* at 5. Registrant has further admitted that he failed to provide adequate patient records to one group of state officials, then provided fraudulent patient records to another group of state officials. *Id.* As such, the Agency finds that Registrant violated 21 CFR 1306.04(a) and South Carolina Code §§ 40–47–110 and 40–47–113.

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Registrant's registration and thus finds Registrant's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Registrant failed to provide any evidence to rebut the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has established grounds for revocation, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). To establish that he can be entrusted with registration, a registrant must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62316, 62339 (2012); *see also Michele L. Martinho, M.D.,* 86 FR 24012, 24019 (2021); *George D. Gowder, III, M.D.,* 89 FR 76152, 76154 (2024). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33738, 33746 (2021).

Here, Registrant failed to answer the allegations contained in the OSC and did not otherwise avail himself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to his future compliance with the CSA nor made any demonstration that he can be entrusted with registration. Moreover, the evidence presented by the Government shows that Registrant violated the CSA, further indicating that Registrant cannot be entrusted.

Accordingly, the Agency will order the revocation of Registrant's registration.

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. BR6910803 issued to David Carlos Rodriguez, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of David Carlos Rodriguez, M.D., to renew or modify this registration, as well as any other pending application of David Carlos Rodriguez, M.D., for additional registration in South Carolina. This Order is effective November 22, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 15, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–24575 Filed 10–22–24; 8:45 am]

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[6] South Carolina Code of Regulations § 81–60, entitled Principles of Medical Ethics, states in subsection A that ''a physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.''

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1438]

Bulk Manufacturer of Controlled Substances Application: Irvine Labs, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Irvine Labs, Inc. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before December 23, 2024. Such persons may also file a written request for a hearing on the application on or before December 23, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 26, 2024, Irvine Labs, Inc., 7305 Murdy Circle, Huntington Beach, California 92647–3533, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols ...	7370	I

The applicant plans to manufacture bulk Active Pharmaceutical Ingredients for product development and distribution to DEA-registered researchers. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2024–24554 Filed 10–22–24; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

BRX Pharmacy; Decision and Order

On October 2, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to BRX Pharmacy of Stafford, Texas (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) A, at 1. The OSC/ISO informed Registrant of the immediate suspension of its DEA Certificate of Registration, Control No. FB7301497, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrant's registration, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C.823(g)(1), 824(a)(4)).

The OSC/ISO notified Registrant of its right to file with DEA a written request for hearing. *Id.* at 10–11 (citing 21 CFR 1301.43). The OSC/ISO also notified Registrant that if it requested a hearing but failed to timely file an answer, it would be deemed to have waived its right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43(c)(2), (c)(3), (d)). On October 30, 2023, Registrant timely requested a hearing, however, Registrant failed to answer the allegations of the OSC/ISO. RFAA, at 1; RFAAX C, at 1.[1] The matter was assigned to a DEA Administrative Law Judge (ALJ) who issued an Order for Prehearing Statements that, among other things, reminded Registrant to file a compliant answer within 30 days of receipt of the OSC/ISO.[2] RFAA, at 1; RFAAX C, at 2. On November 7, 2023, Registrant filed an answer, but the ALJ found it ''substantively non-compliant'' and ordered Registrant to refile. RFAA, at 2; RFAAX B, at 4–8; RFAAX D, at 1. Registrant ultimately failed to file a compliant answer. RFAA, at 2; RFAAX E, at 2. On November 13, 2023, the Government filed a Motion to Terminate Proceedings based on Registrant's failure to file an answer. RFAA, at 2.[3] Registrant did not file a response. *Id.* On November 27, 2023, the ALJ issued an order finding Registrant in default and terminating proceedings. *Id.;* RFAAX F, at 4–5.

''A default, unless excused, shall be deemed to constitute a waiver of the registrant's . . . right to a hearing and an admission of the factual allegations of the [OSC/ISO].'' 21 CFR 1301.43(e). Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.'' *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 2; *see also* 21 CFR 1316.67.

I. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are admitted.[4] Registrant is deemed to have admitted and the Agency finds that it repeatedly dispensed prescriptions in violation of the minimum practice standards that govern pharmacy practice in Texas. RFAAX A, at 4. Specifically, from at least January 2022 through June 2023, Registrant repeatedly filled controlled substance prescriptions that contained multiple red flags of abuse and/or diversion without addressing or resolving the red flags, in violation of both federal and state law. *Id.* at 4–5.

A. Pattern Prescribing, Substances of Abuse, and Strength and Quantity

Texas regulations identify the following prescribing patterns as red flag factors: ''[T]he pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances . . . .''; ''[P]rescriptions . . . are routinely for controlled substances commonly known to be abused drugs . . . .''; and ''[P]rescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities . . . .'' 22 Tex. Admin. Code §§ 291.29(f)(1), (3), (5); RFAAX A, at 5.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag of pattern prescribing, substances of abuse, and strength and quantity. RFAAX A, at 5. Specifically, between January 2022 and May 2023, Registrant filled prescriptions for oxycodone (a Schedule II opioid) issued by Dr. V.M. to C.B., E.B., K.B., T.H., and O.B. *Id.* Each prescription was for the highest strength of oxycodone, 30 mg, which is known to be frequently abused, and each prescription ranged from 70 to 105 dosage units, approximately 3 or 4 daily doses. *Id.*

[1] Based on the Government's submissions in its RFAA dated November 29, 2023, the Agency finds that service of the OSC/ISO on Registrant was adequate. Specifically, the Government's exhibit titled Notice of Service includes a copy of a Form DEA–12 signed by Registrant's Pharmacist-in-Charge, indicating that Registrant was personally served with the OSC/ISO on October 5, 2023. RFAA, at 1; RFAAX B, at 1, 3.

[2] Because the 30-day deadline for responding to the OSC/ISO, November 4, 2023, fell on a Saturday, the deadline for responding was November 6, 2023.

[3] The Government refers to an ''Exhibit G'' that is not included in the instant RFAA.

[4] The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan* v. *United States,* 142 S. Ct. 2,370 (2022) (decided in the context of criminal proceedings).