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]

BILLING CODE 4410–09–P

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).

Further, between January 2022 and June 2023, Registrant filled prescriptions for hydrocodone-acetaminophen (a Schedule II opioid) issued by Dr. V.M. to C.A., C.S., J.M., J.S., J.M2., and T.S. *Id.* Each prescription was for the highest strength of hydrocodone-acetaminophen, 10/325 mg, which is known to be frequently abused, and the prescriptions ranged from 100 to 104 dosage units, approximately 4 daily doses. *Id.*

Accordingly, the Agency finds that Registrant filled all these prescriptions without first resolving the prescriptions' red flags of pattern prescribing, substances of abuse, and strength and quantity. *Id.*

B. Controlled Substances Prescribed With Non-Controlled Substances

Texas regulations identify the following prescribing pattern as a red flag factor: ''[D]angerous drugs or over-the-counter products [OTC] . . . are consistently added by the prescriber to prescriptions for controlled substances presented to the pharmacy, indicating a lack of individual drug therapy . . . .'' 22 Tex. Admin. Code § 291.29(f)(6); RFAAX A, at 6.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag of similar prescriptions for controlled substances with OTC products issued by the same practitioner. RFAAX A, at 6. Specifically, between January 2022 and June 2023, Registrant filled prescriptions issued by Dr. V.M. to the eleven individuals listed above for opioids in combination with non-steroidal anti-inflammatory drugs, muscle relaxers, laxatives, and multi-vitamins. *Id.*

Accordingly, the Agency finds that Registrant filled all these prescriptions without first resolving the red flag of controlled substances being prescribed with non-controlled OTC products. *Id.*

C. Shared Addresses

Texas regulations identify the following prescribing pattern as a red flag factor: ''[M]ultiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner.'' 22 Tex. Admin. Code § 291.29(f)(11); RFAAX A, at 6.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag of patients with the same address presenting the same, or substantially similar, prescriptions from the same practitioner. RFAAX A, at 6. Specifically, between January 2022 and May 2023, Registrant filled prescriptions for oxycodone 30 mg for E.B. and K.B., who both share the same address and received their prescriptions from the same practitioner, Dr. V.M. *Id.* Moreover, between January 2022 and May 2023, Registrant filled prescriptions for hydrocodone-acetaminophen 10/325 mg for J.M., J.M2., and T.S., who all share the same address and received their prescriptions from the same practitioner, Dr. V.M. *Id.*

Accordingly, the Agency finds that Registrant filled all these prescriptions without first resolving the red flag of patients with the same address presenting the same, or substantially similar, prescriptions from the same practitioner. *Id.*

D. Cash Payments

Texas regulations identify the following prescribing pattern as a red flag factor: ''[P]ersons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.'' 22 Tex. Admin. Code § 291.29(f)(12); RFAAX A, at 6–7.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag of cash payments, which is a common red flag because it allows a patient to avoid the scrutiny associated with the use of insurance. RFAAX A, at 6–7. Specifically, between January 2022 and June 2023, Registrant routinely accepted cash payments for controlled substance prescriptions, including all of the prescriptions for the eleven individuals described above. *Id.* at 7.[5]

Accordingly, the Agency finds that Registrant filled all these prescriptions without first resolving the red flag of routinely accepting cash payments for controlled substance prescriptions. *Id.*

E. Prescriber Area of Practice

Texas regulations identify the following prescribing pattern as a red flag factor: ''[T]he controlled substance(s) or the quantity of the controlled substance(s) prescribed are inconsistent with the practitioner's area of medical practice.'' 22 Tex. Admin. Code § 291.29(f)(9); RFAAX A, at 7. Registrant is deemed to have admitted that between January 2022 and June 2023, Registrant repeatedly filled prescriptions for oxycodone and hydrocodone-acetaminophen issued by Dr. V.M., despite Dr. V.M. prescribing outside her family and administrative medicine area of practice. RFAAX A, at 7.[6] Accordingly, the Agency finds that Registrant filled all these prescriptions without first resolving the red flag arising from the prescriber's area of practice.

F. Long Distances

Registrant is deemed to have admitted that it repeatedly filled prescriptions without identifying and resolving the red flag of patients traveling long distances to obtain or fill controlled substance prescriptions.[7] RFAAX A, at 7–8. Specifically, Registrant is deemed to have admitted that it filled prescriptions for at least four individuals, E.B., K.B., C.B., and C.S., whose residences were in ''completely opposite areas of the Houston Metropolitan area'' from their physician's office (Dr. V.M.) and from their pharmacy (Registrant). *Id.* Registrant further admits that there were several pharmacies closer to both Dr. V.M.;s office and the four individuals' residences. *Id.*

Accordingly, the Agency finds that Registrant filled all these prescriptions without first resolving the red flag of patients traveling long distances to fill prescriptions for controlled substances. *Id.*

G. Other Red Flags [8]

Registrant is deemed to have admitted that it repeatedly filled controlled substance prescriptions when it had reason to doubt the accuracy or legitimacy of the prescriptions, and did so without identifying and resolving this red flag. *Id.* at 8–9. For example,

[5] This Decision and Order does not address allegations concerning the high cash payment/high pricing red flag due to the number and egregiousness of the rest of the allegations. *Coconut Grove Pharmacy,* 89 FR 50,372, 50,375 n.20 (2024).

[6] Texas regulations further identify as a red flag pattern, ''[T]he practitioner's clinic is not registered as, and not exempted from registration as, a pain management clinic by the Texas Medical Board, despite prescriptions by the practitioner presented to the pharmacy indicating that the practitioner is mostly prescribing opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone, or any combination of these drugs.'' 22 Tex. Admin. Code § 291.29(f)(8). The OSC alleges, and it is therefore deemed admitted, that ''Dr. [V.M.] is not Board Certified in the area of pain management.'' RFAAX A, at 6. However, there is not substantial evidence or an admission that the prescriptions issued by Dr. V.M. that were presented to the Registrant were *mostly* for opioids and the other listed controlled substances. Accordingly, the Agency cannot sustain this allegation or find that it presents an additional instance of the prescriber area of practice red flag.

[7] Though long distances are not specifically mentioned in the Texas regulations, *see infra* II.B., the OSC/ISO notes that the Agency has found that traveling long distances to obtain or fill controlled substance prescriptions is an additional, well-known red flag of abuse and/or diversion. *Id.*

[8] Although the OSC/ISO refers to the following alleged conduct as ''Other Red Flags,'' these forms of alleged conduct are not specifically listed in the Texas regulations as red flags under 22 Tex. Admin. Code § 291.29(f). *See infra* II.B. Instead, the following alleged conduct constitutes violations of 22 Tex. Admin. Code § 291.29(a)–(b) *See infra* II.B.

Registrant repeatedly filled prescriptions for individuals who, despite receiving controlled substances for supposedly chronic pain, were filling their prescriptions late. *Id.* at 8. On November 1, 2022, Registrant filled a prescription for oxycodone 30 mg for T.H. approximately seven days after the prescription was written. *Id.* On November 21, 2022, Registrant filled a prescription for oxycodone 30 mg for K.B. approximately eleven days after the prescription was written. *Id.* On February 16, 2023, Registrant filled a prescription for hydrocodone-acetaminophen 10/325 mg for J.S. nine days after the prescription was written. *Id.* Lastly, on March 23, 2023, and April 27, 2023, Registrant filled prescriptions for oxycodone 30 mg for O.B. ten or more days after the prescriptions were written. *Id.*

Moreover, Registrant repeatedly filled prescriptions for controlled substances when there were months when the prescriptions were neither prescribed nor filled. *Id.* Between November 16, 2022, and February 28, 2023, C.A. failed to have a monthly controlled prescription filled, but filled other non-controlled prescriptions at Registrant. *Id.* Between October 18, 2022, and April 12, 2023, J.M2. failed to have a monthly controlled prescription filled. *Id.* at 9. Between November 23, 2022, and March 3, 2023, as well as between March 3, 2023, and June 5, 2023, C.S. failed to have a monthly controlled prescription filled, but filled other non-controlled prescriptions at Registrant. *Id.* Between November 17, 2022, and February 16, 2023, J.S. failed to have a monthly controlled prescription filled, but filled other non-controlled prescriptions at Registrant. *Id.* Between April 28, 2022, and October 18, 2022, as well as between November 22, 2022, and May 4, 2023, J.M. failed to have a monthly controlled prescription filled, but filled other non-controlled prescriptions at Registrant. *Id.* Between February 13, 2023, and May 2, 2023, K.B. failed to have a monthly controlled prescription filled, but filled other non-controlled prescriptions at Registrant. *Id.* Between November 1, 2022, and April 25, 2023, T.H. failed to have a monthly controlled prescription filled. *Id.* Finally, between September 15, 2022, and February 15, 2023, O.B. failed to have a monthly controlled prescription filled at Registrant, while on November 13, 2022, O.B. filled a controlled prescription at another pharmacy. *Id.*

Registrant is also deemed to have admitted that it dispensed prescriptions for high dosages of controlled substances that, in combination with other substances, can cause respiratory depression and can lead to coma or death. *Id.* Specifically, Registrant dispensed oxycodone and cyclobenzaprine (a non-scheduled muscle relaxer) together to E.B. approximately eleven times. *Id.* Registrant also dispensed oxycodone and either gabapentin (a non-scheduled anticonvulsant) or tizanidine (a non-scheduled muscle relaxer) together to K.B. approximately seven times. *Id.*

Accordingly, the Agency finds that Registrant filled all these prescriptions without first resolving the red flags of late fills, gaps in filling prescriptions, and high dosages of controlled substances in dangerous combinations. *Id.*

H. Expert Review

DEA retained an independent pharmacy expert who concluded that the above prescription data presented multiple red flags that were highly indicative of abuse and diversion. *Id.* Registrant is deemed to have admitted and the Agency finds that these red flags were not resolved by a pharmacist acting in the usual course of professional practice prior to dispensing, and, therefore, that each prescription was filled outside the Texas standard of care. *Id.*

II. Discussion

A. The Five Public Interest Factors

Under the Controlled Substances Act (CSA), ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under [21 U.S.C. 823] inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant]'s experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant]'s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),[9] the Government's evidence in support of its *prima facie* case for revocation of Registrant's registration is confined to Factors B and D. *See* RFAAX A, at 5. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government's evidence satisfies its *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualeh Ashraf, M.D.,* 88 FR 1,095, 1,097 (2023); *Kareem Hubbard, M.D.,* 87 FR 21,156, 21,162 (2022). In the current matter, the Government has alleged that Registrant violated both federal and state law regulating controlled substances. RFAAX A, at 2–4.

Specifically, a pharmacist may only fill a prescription that was ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' *Id.* § 1306.04(a). Although ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist

[9] As to Factor A, the record contains no evidence of a recommendation from any state licensing board or professional disciplinary authority. 21 U.S.C. 823(g)(1)(A). Nonetheless, an absence of such evidence ''does not weigh for or against a determination as to whether continuation of the [registrant's] DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011). As to Factor C, there is no evidence in the record that Registrant has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010). Finally, as to Factor E, the Government's evidence fits squarely within the parameters of Factors B and D and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Registrant.

who fills the prescription.'' *Id.* Section 1306.04(a) prohibits ''a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose.'' *Wheatland Pharmacy,* 78 FR 69,441, 69,445 (2013) (internal quotations and alterations omitted); RFAAX 2, at 2. DEA regulations require ''pharmacists to identify and resolve suspicions that a prescription is illegitimate.'' *Trinity Pharmacy II,* 83 FR 7,304, 7,331 (2018); RFAAX 2, at 2. Further, under federal regulations, a prescription for a controlled substance ''may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06.

As for state law, under Texas regulations, ''[a] pharmacist may not dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice.'' Tex. Health & Safety Code § 481.074(a). Regarding the specific standards for a pharmacist filing a new or refill prescription, ''[f]or the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant: . . . (III) reasonable dose and route of administration; . . . (VI) drug-drug interactions; . . . [and] (X) proper utilization, including overutilization or underutilization.'' 22 Tex. Admin. Code § 291.33(c)(2)(A)(i). ''Upon identifying any clinically significant conditions [or] situations . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.'' *Id.* § 291.33(c)(2)(A)(ii). ''Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained.'' *Id.* § 291.33(c)(2)(A)(iv); *see also id.* §§ 291.29(a)–(b), 291.33(c)(2)(C) (describing the requirements for documentation).

Regarding ''red flag factors'' that are ''relevant to preventing the non-therapeutic dispensing of controlled substances,'' Texas regulations identify the following relevant circumstances as red flags:

(1) the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner; . . .

(3) prescriptions by a prescriber presented to the pharmacy are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups containing codeine, or any combination of these drugs;

(4) prescriptions for controlled substances by a prescriber presented to the pharmacy contain nonspecific or no diagnoses, or lack the intended use of the drug;

(5) prescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities (*e.g.,* monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner; . . .

(8) the practitioner's clinic is not registered as, and not exempted from registration as, a pain management clinic by the Texas Medical Board, despite prescriptions by the practitioner presented to the pharmacy indicating that the practitioner is mostly prescribing opioids . . . ;

(9) the controlled substance(s) or the quantity of the controlled substance(s) prescribed are inconsistent with the practitioner's area of medical practice; . . .

(11) multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner; [and]

(12) persons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.''

Id. § 291.29(f). Further, under Texas regulations, ''[a] pharmacist shall not dispense a prescription drug if the pharmacist knows or should know the prescription drug order is fraudulent or forged.''*Id.*

Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant repeatedly filled prescriptions for controlled substances that contained multiple red flags of abuse and/or diversion without addressing or resolving those red flags. RFAAX A, at 5–9. DEA's pharmacy expert concluded that these red flags were highly indicative of abuse and diversion. *Id.* at 9. Registrant has further admitted that none of the above-referenced controlled substance prescriptions were filled for a legitimate medical purpose in the usual course of professional practice. *Id.* As such, the Agency finds that Registrant violated 21 CFR 1306.04, 1306.06; Texas Health & Safety Code § 481.074; and 22 Texas Administrative Code §§ 291.29, 291.33.

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 it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018). To establish that it can be entrusted with registration, a registrant must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62,316, 62,339 (2012) (internal quotations omitted); *see also Michele L. Martinho, M.D.,* 86 FR 24,012, 24,019 (2021); *George D. Gowder, III, M.D.,* 89 FR 76,152, 76,154 (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 33,738, 33,746 (2021).

Here, Registrant failed to answer the allegations contained in the OSC/ISO and did not otherwise avail itself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to its future compliance with the CSA nor made any demonstration that it 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. FB7301497 issued to BRX Pharmacy. 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 BRX Pharmacy to renew or modify this

registration, as well as any other pending application of BRX Pharmacy for additional registration in Texas. 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. 2024–24564 Filed 10–22–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Itani Family Pharmacy, PLC; Decision And Order

On June 1, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Itani Family Pharmacy, PLC, of Titusville, Florida (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, Attachment (Attach.) A (hereinafter, OSC/ISO), at 1, 6. The OSC/ISO informed Registrant of the immediate suspension of its DEA registration, No. FI2917702,[1] 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.* at 1 (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 within 30 days after the date of receipt of the OSC/ISO. OSC/ISO, at 5–6 (citing 21 CFR 1301.43(a)). The OSC/ISO also notified Registrant that if it failed to file such a request, it would be deemed to have waived its right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43(c)). The OSC/ISO further notified Registrant that ''[d]efault constitutes a waiver of [Registrant's] right to a hearing and an admission of the factual allegations of this [OSC/ISO].'' *Id.* (citing 21 CFR 1301.43(e)).

On June 19, 2023, the OSC/ISO was personally served on Registrant's owner and pharmacist-in-charge (PIC), Mr. Basil Itani. RFAAX 1, at 1. On June 30, 2023, a purported request for hearing was filed with the DEA Office of Administrative Law Judges (OALJ) and assigned to the Chief Administrative Law Judge (Chief ALJ). RFAA, at 2. A prehearing conference was then held on July 27, 2023. RFAA, at 2; RFAAX 2, at 2; RFAAX 4, at 1–2.

On September 22, 2023, the Government filed a motion to terminate the proceedings. RFAAX 2, at 4–5. In the motion, the Government represented that after the July 27 prehearing conference, ''it came to DEA's attention that Mr. Basil Itani was unaware of any administrative proceedings that had taken place'' and that he had ''no interest in proceeding forward with the administrative hearing.'' *Id.* at 2. The Government further represented that Mr. Itani had informed DEA that he did not have interest in proceeding with a hearing, and ''only his father . . . would possess any interest in moving forward with the DEA administrative hearing.'' *Id.* After learning this information, Government counsel notified the attorney who filed the hearing request (hereinafter, Counsel) that the Government would file a motion to terminate the proceedings unless Counsel provided the Government with evidence ''that [Counsel] represented [Mr. Itani] and his interests in this administrative hearing.'' *Id.* The Government never received any response to this request and filed a motion to terminate, arguing that Registrant's hearing request ''was made without authority'' because Mr. Itani—the only individual who had authority to request a hearing [2]—did not ''provide express authority to request a hearing on behalf of the pharmacy.'' *Id.* at 3–5.

On September 28, 2023, the Chief ALJ ordered Counsel to ''provide . . . a notarized power of attorney showing the requisite authority to act as a representative [of Registrant] in these administrative enforcement proceedings.'' RFAAX 3 (citing 21 CFR 1316.50). Counsel never responded to the Government's motion to terminate or the Chief ALJ's directive, and never produced any evidence demonstrating that he had authority to represent Registrant. RFAAX 4, at 1, 3. Based on Registrant's failure to respond, on October 5, 2023, the Chief ALJ granted the Government's unopposed motion and terminated proceedings, finding that ''there is simply no basis upon which to conclude that [Counsel] has authority to act on behalf of [Registrant], or that the [request for hearing] in this case is valid.'' *Id.* at 4.

The Agency agrees with the Chief ALJ. Counsel was given three opportunities to demonstrate that he was authorized to request a hearing for Registrant after the Government learned that Mr. Itani was unaware of the proceedings and had no interest in participating. In response to these opportunities, Counsel remained silent. Indeed, by the time the Chief ALJ terminated the case, it had been over two months since Counsel had communicated with OALJ or made any filings in the matter. RFAAX 4, at 2 nn.3–4. Despite multiple requests, Counsel remained silent and, as the Chief ALJ found, failed to demonstrate that he had the authority to act for Registrant.[3] RFAAX 4, at 3–4.

Accordingly, the Agency finds that a valid hearing request was never filed in this matter and, consequently, that Registrant is deemed to be in default.[4] 21 CFR 1301.43(c)(1). ''A default, unless

[1] The record represents that this registration expired on November 30, 2023. RFAAX 1, at 1. The fact that a registrant allows its registration to expire during the pendency of an administrative enforcement proceeding does not impact the Agency's jurisdiction or prerogative to adjudicate the OSC/ISO to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68479 (2019).

[2] The Agency agrees with the Government and the Chief ALJ that the only individual with authority to request a hearing on Registrant's behalf was its owner and PIC, Mr. Itani, as he has been Registrant's only managing member and is the sole signatory and contact on Registrant's registration. RFAAX 2, at 2–4; RFAAX 4, at 3–4; *see also infra* note 3.

[3] *See supra* note 2. Given the Government's unrefuted representations that Mr. Itani was unaware that a hearing had been requested and that he had no interest in a hearing, the Agency views Counsel's extended silence in the face of multiple requests as sufficient evidence that the hearing request was not filed upon the direction of Mr. Itani, the only person entitled to request a hearing for Registrant.

[4] Even if the hearing request had been valid, Registrant would be deemed to be in default based on its ''fail[ure] to plead . . . or otherwise defend'' itself. *See* 21 CFR 1301.43(c)(3) (''In the event . . . a person who has requested a hearing fails to plead . . . or otherwise defend, said party shall be deemed to be in default and the opposing party may move to terminate the proceeding.''). Here, as the Chief ALJ found, Registrant waived its right to a hearing by failing to respond to the Government's motion to terminate, failing to respond to chambers staff at the Chief ALJ's direction, failing to file exhibits, and failing to file a notarized power of attorney as ordered by the Chief ALJ. RFAAX 4, at 4.