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.

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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.

excused, shall be deemed to constitute a waiver of [Registrant's] right to a hearing and an admission of the factual allegations of the [OSC/ISO].'' 21 CFR 1301.43(e). To date, Registrant has not filed a motion to excuse the default with the Office of the Administrator.

''In 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.'' 21 CFR 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), because Registrant has not timely requested a hearing, nor timely moved to excuse the default, nor filed a motion with the Administrator seeking to excuse the default. *See also id.* § 1316.67.

I. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are deemed to be admitted.[5] 21 CFR 1301.43(e). Accordingly, Registrant admits that from January 5, 2023, to May 24, 2023, on nine separate occasions, Registrant dispensed controlled substances to a confidential informant (CI) in exchange for cash. OSC/ISO, at 2–4. On each occasion, Registrant admits that the CI did not present any prescription and that Registrant dispensed the controlled substances despite the absence of a prescription. *Id.* Registrant admits that the controlled substances dispensed and the cash received by Registrant on each of the nine occasions are as follows:

Date	Controlled substances	Units (pills)	Cash received
January 5, 2023	Methadone[6] 10 mg	200	$600
January 18, 2023	Oxycodone[7] 15 mg	15	1,000
	Morphine[8] 15 mg	100	
	Methadone 10 mg	100	
	Methylphenidate[9] 5 mg	18	
	Alprazolam[10] 2 mg	100	
February 2, 2023	Oxycodone 5 mg	500	2,000
	Alprazolam 2 mg	99	
February 15, 2023	Oxycodone 5 mg	500	2,000
	Methadone 10 mg	100	
March 2, 2023	Oxycodone 5 mg	500	2,000
	Alprazolam 2 mg	100	
March 23, 2023	Oxycodone 5 mg	500	2,000
	Methadone 10 mg	100	
April 12, 2023	Oxycodone 5 mg	500	2,000
	Methadone 10 mg	200	
May 4, 2023	Oxycodone 5 mg	500	2,000
	Oxycodone 20 mg	3.5	
	Methadone 10 mg	200	
May 24, 2023	Oxycodone 5 mg	500	2,000
	Methadone 10 mg	200	
Totals		5,035.5	15,600

See OSC/ISO, at 2–4.

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 his 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).

When making this determination, DEA considers the 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).

[5] The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan* v. *United States,* 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

[6] Methadone is a schedule II opioid. OSC/ISO, at 3; *see also* 21 CFR 1308.12(c)(15).

[7] Oxycodone is a schedule II opioid. OSC/ISO, at 3; *see also* 21 CFR 1308.12(b)(1)(xiv).

[8] Morphine is a schedule II opioid. OSC/ISO, at 3; *see also* 21 CFR 1308.12(b)(1)(ix).

[9] Methylphenidate is a schedule II stimulant. OSC/ISO, at 3; *see also* 21 CFR 1308.12(d)(4).

[10] Alprazolam is a schedule IV depressant. OSC/ISO, at 3; *see also* 21 CFR 1308.14(c)(2).

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1),[11] the Government's evidence in support of its *prima facie* case for sanction is confined to factors B and D. OSC/ISO, at 2. The Government has the burden of proof in this proceeding. 21 CFR 1301.44.

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

1. 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. *Blue Mint Pharmacy,* 88 FR 75,326, 75,329 (2023).

In the current matter, the Government has alleged that Registrant violated federal and Florida laws regulating controlled substances. OSC/ISO, at 1–6. Specifically, federal law provides that ''no controlled substance in schedule II . . . may be dispensed without the written prescription of a practitioner.'' *Id.* at 2–4 (citing 21 U.S.C. 829(a)). Similarly, it is unlawful in Florida for any person to ''sell or dispense [12] drugs . . . without first being furnished with a prescription.'' OSC/ISO, at 2 (citing Fla. Stat. § 465.015(2)(c)). Furthermore, Florida law provides that ''dispensing, or distributing . . . any controlled substance, other than in the course of the professional practice of pharmacy'' is ''grounds for denial of a license or disciplinary action.'' *Id.* (citing Fla. Stat. § 465.016(1)(i)).

Here, Registrant admits that from January 5, 2023, to May 24, 2023, it dispensed over 5,035 controlled substance pills to CI without a prescription, which is a clear violation of federal and Florida law. OSC/ISO, at 2–4. Registrant additionally admits that this misconduct reflects negative experience in dispensing controlled substances. *Id.* at 2.

Specifically, Registrant admits that it dispensed 3,518.5 pills of oxycodone, 1,100 pills of methadone, 299 pills of alprazolam, 100 pills of morphine, and 18 pills of methylphenidate (5,035.5 pills in total) over the course of nine separate occasions. OSC/ISO, at 2–4. Among these, 4,736.5 pills were for controlled substances in schedule II. *Id.* Registrant further admits that no prescriptions were presented on any of the occasions when these controlled substances were dispensed. *Id.* Registrant also admits that it received a total of $15,600 in cash to dispense these controlled substances without a prescription. *Id.*

Based on Registrant's admissions, the Agency sustains the Government's uncontroverted allegations that Registrant violated federal and Florida laws by dispensing controlled substances without a prescription. OSC/ISO, at 2–4; 21 U.S.C. 829(a); Fla. Stat. §§ 465.015(2)(c), 465.016(1)(i).

In sum, the Agency finds Registrant's continued registration to be inconsistent with the public interest after balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Registrant failed to provide sufficient evidence to rebut the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Registrant's registration, 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 18882, 18910 (2018). ''[T]rust is necessarily a fact-dependent determination based'' on individual circumstances; therefore, the Agency looks at factors such as ''the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior'' and ''the Agency's interest in deterring similar acts.'' *Robert Wayne Locklear, M.D.,* 86 FR 33738, 33746 (2021). To be effective, acceptance of responsibility must be unequivocal. *Mohammed Asgar, M.D.,* 83 FR 29569, 29573 (2018). When a registrant has committed acts inconsistent with the public interest, it must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62339 (2012); *see also George D. Gowder, III, M.D.,* 89 FR 76152, 76154 (2024); *Michele L. Martinho, M.D.,* 86 FR 24012, 24019 (2021).

Here, Registrant did not request a hearing or otherwise avail itself of the opportunity to refute the Government's case. RFAA, at 3; 21 CFR 1301.43(c)(1), (e), (f)(1). As such, the record does not contain any representations from Registrant demonstrating future compliance with the CSA, trustworthiness regarding the responsibilities of holding a DEA registration, acceptance of responsibility, or remedial measures.

Accordingly, in light of Registrant's default and the lack of mitigating evidence, 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. FI2917702 issued to Itani Family Pharmacy, PLC. 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 Itani Family Pharmacy, PLC, to renew or modify this registration, as well as any other pending application of Itani Family Pharmacy, PLC, for additional registration in Florida. 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.

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[11] 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 any federal or state law offense ''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). 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.

[12] Florida law defines ''dispense'' as ''the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer.'' Fla. Stat. § 465.003(13). The CSA defines ''dispense'' as the ''deliver[y] [of] a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner . . . .'' 21 U.S.C. 802(10). The CSA defines ''deliver'' and ''delivery'' as ''the actual, constructive, or attempted transfer of a controlled substance . . . .'' *Id.* § 802(8).