Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. Government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on January 16, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 16, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–01563 Filed 1–22–25; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Xubex Community Pharmacy; Decision and Order

On May 29, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Xubex Community Pharmacy of Casselberry, Florida (Respondent). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, (hereinafter, OSC/ISO), at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA registration, No. FX3643081, pursuant to 21 U.S.C. 824(d), alleging that Respondent'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 Respondent's registration, alleging that Respondent'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 Respondent of its right to file with DEA a written request for a hearing within 30 days after the date of receipt of the OSC/ISO. OSC/ISO, at 4 (citing 21 CFR 1301.43(a)). The OSC/ISO also notified Respondent 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), (d)). The OSC/ISO further notified Respondent that ''[d]efault constitutes a waiver of [Respondent's] right to a hearing and an admission of the factual allegations of this [OSC/ISO].'' *Id.* (citing 21 CFR 1301.43(e)).

The RFAA asserts that on June 6, 2024, a DEA Diversion Investigator personally served the OSC/ISO on ''a representative of Respondent.'' RFAA, at 1.[1] On June 9, 2024, Mr. M.H.[2] communicated via email to the Government that he represented Respondent and ''[Respondent] was taking the default.'' RFAAX 2, at 1. Accordingly, based on Respondent's failure to request a hearing, answer, or otherwise plead or defend the allegations delineated in the OSC/ISO, the Agency finds that Respondent is deemed to be in default. 21 CFR 1301.43(c). ''A default, unless excused, shall be deemed to constitute a waiver of [Respondent's] right to a hearing and an admission of the factual allegations of the [OSC/ISO].'' 21 CFR 1301.43(e). To date, Respondent 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 Respondent's default pursuant to 21 CFR 1301.43(c), (f), because Respondent did not request a hearing or file an answer, and it has not filed a motion with the Administrator seeking to excuse the default. *See also id.* § 1316.67.

[1] The RFAA does not include an affidavit from the DEA Diversion Investigator or any other documentary evidence regarding the method of service; however, the Agency can conclude based on the email from Mr. M.H. that Respondent actually received the OSC and therefor that service was proper.

[2] Mr. M.H. is ''part owner of the [Xubex Community] Pharmacy.'' RFAA, at 2.

I. Findings of Fact

The Agency finds that, in light of Respondent's default, the factual allegations in the OSC/ISO are deemed to be admitted.[3] 21 CFR 1301.43(e). Accordingly, Respondent admits and the Agency finds substantial evidence that on two separate occasions, Respondent dispensed Schedule II controlled substances to a confidential source (CS) in exchange for cash without a prescription being presented for the controlled substances. OSC/ISO, at 3. Specifically, Respondent admits and the Agency finds substantial evidence that on November 30, 2023, it dispensed ten oxycodone[4] tablets to CS in exchange for $260 in the absence of a prescription. *Id.* Additionally, Respondent admits and the Agency finds substantial evidence that on December 19, 2023, Respondent dispensed two hydromorphone[5] tablets to CS in exchange for $50 in the absence of a prescription. *Id.*

II. Discussion

A. The CSA and the OSC Allegations

Pursuant to the CSA, ''[a] registration . . . to . . . distribute[ ] or 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 by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[6] The five factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. 243, 292–93 (2006) (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' (citing *In*

[3] 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).

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

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

[6] The five factors of 21 U.S.C. 823(g)(1)(A–E) are:

(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.

re Arora, 60 FR 4447, 4448 (1995))); *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (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. *Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007); *Morall,* 412 F.3d. at n.2; *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

In this matter, while all of the 21 U.S.C. 823(g)(1) factors have been considered, the Agency finds that the Government's evidence in support of its *prima facie* public interest revocation case is confined to factors B and D.[7] *See* OSC/ISO, at 3–4.

According to DEA regulations, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied.'' 21 CFR 1301.44(e); *see also Morall,* 412 F.3d. at 174; 21 CFR 1301.44(d) (applying the same standard to a ''denial of a registration'').

B. Improper Dispensing and Public Interest Analysis

In the current matter, the Government has alleged that Respondent violated federal and Florida laws regulating controlled substances. OSC/ISO, at 1–5. Specifically, federal law provides that ''no controlled substance in schedule II . . . may be dispensed without the written prescription of a practitioner.'' 21 U.S.C. 829(a); *see* OSC/ISO, at 2–3. Similarly, it is unlawful in Florida for any person to '' 'sell or dispense[8] drugs . . . without first being furnished with a prescription.' '' OSC/ISO, at 2 (citing Fla. Stat. section 465.015(2)(c)).

Here, the Agency finds substantial record evidence that on November 30, 2023, and December 19, 2023, Respondent dispensed Schedule II controlled substances to CS without a prescription, which is a clear violation of Federal and Florida law. 21 U.S.C. 829(a) and 823(g)(1)(D); Fla. Stat. section 465.015(2)(c). The Agency further finds that this misconduct demonstrates Respondent's negative experience in dispensing controlled substances. 21 U.S.C. 823(g)(1)(B). Accordingly, the Agency concludes that Respondent's continued registration is inconsistent with the public interest. *Id.* sec. 823(g)(1).

As Respondent failed to request a hearing, he has waived the opportunity to present evidence and, therefore, to rebut the Government's *prima facie* case. The Government's *prima facie* case was established by substantial record evidence. *Supra* Section I. Accordingly, the Agency finds that there is substantial and uncontroverted record evidence supporting the revocation of Respondent's registration. 21 U.S.C. 824(a)(4).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration would be inconsistent with the public interest, the burden shifts to Respondent to show why he can be entrusted with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.,* 83 FR 18882 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy,* 881 F.3d at 833; *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995). A registrant's acceptance of responsibility must be unequivocal. *Jones Total Health Care Pharmacy,* 881 F.3d at 830–31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, the Agency has found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. The Agency has also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR 46972 and 46973.

Regarding these matters, there is no record evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the founded violations meaning, among other things, that it is not reasonable to believe that Respondent's future controlled substance-related actions will comply with legal requirements. Accordingly, Respondent did not convince the Agency that he can be entrusted with a registration.

Further, the interests of specific and general deterrence weigh in favor of revocation. Given the foundational nature of Respondent's violations, which more closely resembled drug dealing than legal dispensing, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not a condition precedent to maintaining a registration.

Accordingly, I shall order revocation of Respondent's registration as contained in the Order below.

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. FX3643081 issued to Xubex Community 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 Xubex Community Pharmacy to renew or modify this registration, as well as any other pending application of Xubex Community Pharmacy for additional registration in Florida. This Order is effective February 24, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on January 16, 2025, 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. 2025–01537 Filed 1–22–25; 8:45 am]

BILLING CODE 4410–09–P

[7] As already discussed, the record contains no evidence submitted by Respondent. *Supra.*

[8] 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. section 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.* sec. 802(8).