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

Just Here II Pharmacy; Decision and Order

I. Introduction

On October 24, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registrations (OSC/ISO) to Just Here II Pharmacy, of Philadelphia, Pennsylvania (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Registrant of the immediate suspension of its DEA Certificate of Registration, No. FJ1928689, 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.* at 1–2 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).[1]

More specifically, the OSC/ISO alleged that between September 27, 2023, and March 1, 2024, Registrant failed to maintain accurate records of its inventory, purchasing, and dispensing of controlled substances, in violation of federal and Pennsylvania state law. *Id.* at 2–4 (citing 21 CFR 1304.04(a), 1304.11(a)–(c), 1304.21(a); 35 Pa. Cons. Stat. Ann. §§ 780–112(a)–(c), 780–113(a)(21)).[2] The Government alleges that these recordkeeping failures resulted in Registrant's inability to account for thousands of dosage units of controlled substances during an accountability audit. *Id.* at 1.

On December 13, 2024, the Government submitted a request for final agency action (RFAA) requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 1–4. After carefully reviewing the entire record and conducting the analysis as set forth in more detail below, the Agency grants the Government's request for final agency action and revokes Registrant's registration.

II. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request ''within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default'' unless ''good cause'' is established for the failure. 21 CFR 1301.43(a) & (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is ''deemed to have waived their right to a hearing and to be in default.'' 21 CFR 1301.43(c)(2). Unless excused, a default is deemed to constitute ''an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Here, the OSC/ISO notified Registrant of its right to file with DEA a written request for hearing and 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. RFAAX 2, at 9 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.[3] Thus, the Agency finds that Registrant is in default and therefore has admitted to the factual allegations in the OSC/ISO. 21 CFR 1301.43(e); 21 CFR 1301.43(c)(1).

III. Applicable Law

A. The Alleged Statutory and Regulatory Violations

As discussed above, the OSC/ISO alleges that Registrant violated provisions of the CSA and its implementing regulations. As the Supreme Court stated in *Gonzales* v. *Raich,* 545 U.S. 1 (2005), ''the main objectives of the [Controlled Substances Act (CSA)] were to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances.'' 545 U.S. at 12. *Gonzales* explained that:

> Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA . . . . The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.

Id. at 12–14.

Here, the OSC/ISO's allegations concern the CSA's ''strict requirements regarding registration . . . drug security, and recordkeeping'' and, therefore, go to the heart of the CSA's ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances,'' and ''to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–14, 27.

B. Improper Dispensing, Recordkeeping, and Unaccounted For Controlled Substances

According to the CSA's implementing regulations, pharmacies must maintain ''a complete and accurate record of each controlled substance . . . sold . . . .'' 21 CFR 1304.21(a). This includes conducting and maintaining an ''initial inventory . . . of all stocks of controlled substances on hand on the date [the pharmacy] first engages in the . . . dispensing of controlled substances,'' as well as a ''biennial inventory . . . of all stocks of controlled substances on hand.'' 21 CFR 1304.11(a)–(c). Pharmacies must retain these inventories ''for at least 2 years from the date of such inventory or records, for inspection and copying.'' 21 CFR 1304.04.

Pennsylvania law also requires pharmacies to keep accurate records and maintain proper inventories regarding the purchase, sale, or dispensing of any controlled substances. 35 Pa. Cons. Stat. Ann. § 780–112(a)–(c). In Pennsylvania, it is unlawful for a pharmacy to fail to ''make, keep or furnish any record, notification, order form, statement, invoice or information'' relating to the purchasing or dispensing of a controlled substance. *Id.* § 780–113(a)(21).

[1] According to Agency records, Just Here II Pharmacy's registration expired on December 31, 2024. 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 under the Controlled Substances Act (CSA) to adjudicate the OSC/ISO to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474, 68,476–79 (2019).

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

[3] Based on the Government's submissions in its RFAA dated December 11, 2024, the Agency finds that service of the OSC/ISO on Registrant was adequate. Specifically, the included Declaration from a DEA Diversion Investigator asserts that on October 25, 2024, the OSC/ISO was personally served on Registrant's Pharmacist in Charge, Mr. C.O., at Registrant's registered location. RFAAX 2, at 1.

IV. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are deemed admitted. Registrant is deemed to have admitted that from at least September 27, 2023, until at least March 1, 2024, it failed to maintain accurate records of its purchasing and dispensing of controlled substances. RFAAX 1, at 4. For example, Registrant admits that there were significant discrepancies between the dispensing report that DEA investigators analyzed and Registrant's distributor order data. *Id.* at 3–4. Registrant admits that a comparison of the dispensing report to the distributor order data revealed discrepancies of: (1) approximately 200 dosage units of oxycodone [4] HCL 5 mg, (2) approximately 1,459 dosage units of oxycodone HCL 15 mg, (3) approximately 430 dosage units of oxycodone HCL 20 mg, (4) approximately 287 dosage units of oxycodone-acetaminophen 5/325 mg, (5) approximately 440 dosage units of oxycodone-acetaminophen 10/325 mg, (6) approximately 654 dosage units of alprazolam [5] 0.5 mg, (7) approximately 2,044 dosage units of alprazolam 1 mg, (8) approximately 2,930 dosage units of alprazolam 2 mg, and (9) approximately 2,839 dosage units of promethazine with codeine.[6] *Id.* at 7. These discrepancies amounted to a significant variance between Registrant's dispensing data and distributor order data for each substance, ranging from 33% to 100%.[7] *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant failed to maintain accurate records of its inventory, purchasing, and dispensing of controlled substances. Additionally, Registrant admits, and the Agency finds substantial record evidence that, it failed to adequately maintain an initial or biennial inventory.

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

[5] Alprazolam is a schedule IV benzodiazepine. RFAAX 1, at 4; *see also* 21 CFR 1308.14(c)(2).

[6] Promethazine with codeine is a schedule V opioid. RFAAX 1, at 4; *see also* 21 CFR 1308.15(c)(1).

[7] These discrepancies amounted to a variance of approximately 100% for oxycodone HCL 5 mg, 63.43% for oxycodone HCL 15 mg, 86% for oxycodone HCL 20 mg, 47.83% for oxycodone-acetaminophen 5/325 mg, 33.58% for oxycodone-acetaminophen, 65.40% for alprazolam 0.5 mg, 85.17% for alprazolam 1 mg, 83.71% for alprazolam 2 mg, and 46.15% for promethazine with codeine.

V. Public Interest Determination

A. Legal Background on Public Interest Determinations

When the CSA's requirements are not met, the Attorney General ''may deny, suspend, or revoke [a] registration if . . . the [registrant's] registration would be 'inconsistent with the public interest.' '' *Gonzales* v. *Oregon,* 546 U.S. 243, 251 (2006) (quoting 21 U.S.C. 824(a)(4)). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''pharmacy,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[8]

The five factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. at 292–93 (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' quoting *In re Arora,* 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993); see *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 181 (D.C. Cir. 2005) (describing the Agency's adjudicative process as ''applying a multi-factor test through case-by-case adjudication,'' quoting *LeMoyne-Owen Coll.* v. *N.L.R.B.,* 357 F.3d 55, 61 (D.C. Cir. 2004)). Any one factor, or combination of factors, may be decisive, *David H. Gillis, M.D.,* 58 FR at 37,508, and the Agency ''may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied.'' *Morall,* 412 F.3d. at 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.,* 70 FR 33,207, 33,208 (2007)); *see also Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007).

Moreover, while the Agency is required to consider each of the factors, it ''need not make explicit findings as to each one.'' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44(e).

B. Respondent's Registration Is Inconsistent With the Public Interest

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case for sanction is confined to Factors B and D. RFAA 2–4, RFAAX 1. Evidence is considered under Factors B and D when it reflects compliance or non-compliance with laws related to controlled substances and experience dispensing controlled substances. *Kareem Hubbard, M.D.,* 87 FR 21,156, 21,162 (2022). Here, as found above, Registrant is deemed to have admitted and the Agency finds that between September 27, 2023, and March 1, 2024, Registrant failed to maintain accurate records of its purchasing and dispensing of controlled substances and its inventory. RFAAX 2, at 5–8. Accordingly, the Agency finds substantial record evidence that Registrant violated federal and state law, namely 21 CFR 1304.04(a), 1304.11(a)–(c), 1304.21(a); and 35 Pa. Cons. Stat. Ann. §§ 780–112(a)–(c), 780–113(a)(21).

The Agency further finds that after considering the factors of 21 U.S.C. 823(g)(1) Registrant's continued registration is ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Accordingly, 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)(4). The Agency also finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in spite of the public interest determination, Registrant can be trusted with a registration.

[8] 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.

VI. Sanction

Where, as here, the Government has met the burden of showing that Registrant's continued registration is inconsistent with the public interest, the burden shifts to Registrant to show why it 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, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *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, the Agency requires that a registrant that has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *See 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). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.,* 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.,* 83 FR 29569, 29573 (2018); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 830–31. In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *See Jones Total Health Care Pharmacy,* 881 F.3d at 830–31; *Hoxie,* 419 F.3d at 483–84. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *See Jones Total Health Care Pharmacy,* 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by a registrant and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Here, Registrant did not timely or properly request a hearing and was deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1–2. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrant has thus failed to answer the allegations contained in the OSC and has not otherwise availed 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) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. FJ1928689 issued to Just Here II Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Just Here II Pharmacy to renew or modify the named registrations, as well as any other pending application of Just Here Pharmacy for additional registration in Pennsylvania. This Order is effective August 13, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 8, 2025, by Acting Administrator Robert J. Murphy. 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 LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by Nyrstar Tennessee Mines—Strawberry Plains, LLC.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before August 13, 2025.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2025–0069 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for MSHA–2025–0069.

2. *Fax:* 202–693–9441.

3. *Email: petitioncomments@dol.gov.*

4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, Room C3522, 200 Constitution Ave NW, Washington, DC 20210.

Attention: Jessica D. Senk, Acting Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Jessica D. Senk, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.