



**DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

Immacula Michel, M.D.; Decision and Order

On May 4, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Immacula Michel, M.D., of Greenacres, Florida (Applicant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 4. The OSC proposed the denial of Applicant’s application for DEA registration, Control No. W23121768C, alleging that Applicant’s registration is inconsistent with the public interest. *Id.* at 2 (citing 21 U.S.C. 823(g)(1)(B) and (D)). More specifically, the OSC alleged that Applicant issued three controlled substance prescriptions without a DEA registration in violation of federal and Florida state law. *Id.*

On June 23, 2025, the Government submitted an RFAA requesting that the Agency issue a default final order denying Applicant’s application for registration. RFAA, at 3.¹ 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 denies Applicant’s application for registration.

I. DEFAULT DETERMINATION

Under 21 CFR 1301.43, an applicant 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) and (c)(1). In the absence of a demonstration of good cause, an applicant who fails to timely file an answer is also “deemed to have waived their right to a

¹ The RFAA states that “the Administrator is authorized to render the Agency’s final order, without . . . making a finding of fact.” RFAA, at 3 (citing 21 CFR 1301.43(c), (f), and 1301.46). However, 21 CFR 1316.67 requires that the Administrator’s final order “set forth the final rule and the findings of fact and conclusions of law upon which the rule is based.” *See JYA LLC d/b/a Webb’s Square Pharmacy*, 90 Fed. Reg. 31,244, 31,246 n.7 (2025).

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 notified Applicant of her right to file a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default.^{2,3} RFAAX 1, at 3 (citing 21 CFR 1301.43). Applicant did not request a hearing. RFAA, at 1, 3. Thus, the Agency finds that Applicant is in default and is deemed to have admitted the factual allegations in the OSC. 21 CFR 1301.43(e).

II. APPLICABLE LAW

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.” *Id.* at 12. This case 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.

The CSA requires that “every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the [DEA] a registration.” 21 U.S.C. 822(a)(2); *see also Gonzales v. Raich*, 545 U.S. at 27-28. Under the CSA, “[t]he very definition of a ‘practitioner’ eligible to prescribe includes physicians ‘licensed, registered, or otherwise permitted, by the . . . jurisdiction in which he practices’ to dispense controlled substances.” *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (citing 21 U.S.C. 802(21)). According to DEA regulations, a prescription

² Based on the Government’s submissions in its RFAA dated June 23, 2025, the Agency finds that service of the OSC on Applicant was adequate. The included attachments show that on May 9, 2025, a Diversion Investigator (DI) personally served the OSC on Applicant and Applicant signed a receipt of service. RFAAX 2A, at 4; RFAAX 2B. Accordingly, the Agency finds that the Government’s service of the OSC on Applicant was adequate.

³ The sworn statement from DI begins, “I, [DI], under penalty of perjury, declare and state the following.” RFAAX 2, at 1. This declaration omits the statutory language “...that the foregoing is true and correct.” 28 U.S.C. 1746(2). Accordingly, the Agency will give less weight to DI’s sworn statement as evidence, but notes that DI’s declaration is uncontroverted.

may only be issued by an individual practitioner who is “[a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession” and has been issued a DEA registration.⁴ 21 CFR 1306.03. Additionally, a lawful controlled substance order or prescription is one that is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a); *see also United Prescription Servs., Inc.*, 72 Fed. Reg. 50,397, 50,407 (2007) (“a physician who engages in the unauthorized practice of medicine is not a practitioner acting in the usual course of professional practice.”); *Salman Akbar, M.D.*, 89 Fed. Reg. 82,259 (2024) (the Agency determined that issuing prescriptions without a DEA registration is outside of the usual course of practice); *Linda Sue Cheek, M.D.*, 76 Fed. Reg. 66,972, 66,974 (2011) (“It is also unlawful to dispense a controlled substance without first obtaining a [DEA] registration to do so.”).

III. FINDINGS OF FACT

In light of Applicant’s default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Applicant admits that “[b]etween November 2024 and February 2025, [she] issued three (3) controlled substance prescriptions for phentermine (a Schedule IV controlled substance) under DEA [registration] No. BM6676449, despite having surrendered this DEA [registration] on August 4, 2022.” RFAAX 1, at 2. Therefore, the Agency finds substantial record evidence that Applicant issued three controlled substance prescriptions without a DEA registration. *Id.*

IV. PUBLIC INTEREST DETERMINATION

A. Legal Background on Public Interest Determinations

When the CSA’s requirements are not met, the Agency⁵ “may deny, suspend, or revoke [an application] if . . . the physician’s registration would be ‘inconsistent with the public

⁴ While there are exemptions to the registration requirements, *see* 21 CFR 1301.22-.23, none apply to Applicant.

⁵ The CSA delegates this power to the Attorney General, who has delegated it to the Administrator of the DEA (the Agency) by 28 CFR 0.100.

interest.” *Gonzales v. Oregon*, 546 U.S. at 251 (quoting 21 U.S.C. 824(a)(4)).⁶ In the case of a “practitioner,” the Agency is directed to consider five factors in making the public interest determination. *Id.*; 21 U.S.C. 823(g)(1)(A-E).⁷

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 Fed. Reg. 4,447, 4,448 (1995))); *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.*, 58 Fed. Reg. 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 Fed. Reg. 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 Fed. Reg. 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);

⁶ The Government has the burden of proof in this proceeding. 21 CFR 1301.44(d).

⁷ The five factors are:

- (A) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (B) The applicant’s experience in dispensing, or conducting research with respect to controlled substances.
- (C) The applicant’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)(A-E).

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 Fed. Reg. 459, 462 (2009). Accordingly, as the Eleventh Circuit has recognized, Agency decisions have explained that findings under a single factor can support the denial of an application for registration. *Jones Total Health Care Pharmacy*, 881 F.3d at 830.

B. Applicant’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),⁸ the Government’s evidence in support of its *prima facie* case is confined to Factors B and D. RFAAX 1, at 2. Evidence is considered under Factors B and D when it reflects experience dispensing controlled substances and compliance or non-compliance with laws related to controlled substances. *Kareem Hubbard, M.D.*, 87 Fed. Reg. 21,156, 21,162 (2022).

Here, the Agency found substantial record evidence that between November 2024 and February 2025, Applicant issued three prescriptions for a controlled substance without a DEA registration.⁹ *See supra* Section III. Accordingly, the Agency finds substantial record evidence that Applicant violated both federal and state law, namely 21 CFR 1306.03(a)(2), 1306.04(a), and Florida Statutes § 458.331(1)(g) (2025).¹⁰ Applicant’s misconduct, therefore, reflects negative experience in prescribing with respect to controlled substances and non-compliance

⁸ As to Factor A, there is no record evidence of disciplinary action against Applicant’s state medical license. 21 U.S.C. 823(g)(1)(A). However, “[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent’s DEA certification is consistent with the public interest.” *Roni Dreszer, M.D.*, 76 Fed. Reg. 19,434, 19,444 (2011). As to Factor C, there is no evidence in the record that Applicant 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 Fed. Reg. 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 Applicant.

⁹ There is no record evidence indicating that Applicant qualified for an exemption when these prescriptions were issued. *See, e.g.*, 21 CFR 1301.22-.23.

¹⁰ This Florida statute is violated whenever a licensed physician fails to perform any other statutory or legal obligation placed on them.

with laws related to controlled substances. 21 U.S.C. 823(g)(1)(B), (D); *see also Richard J. Settles, D.O.*, 81 Fed. Reg. 64,940, 64,947 (2016) (finding respondent's registration would be inconsistent with the public interest where he prescribed controlled substances without a DEA registration); *John V. Scalera*, 78 Fed. Reg. 12,092, 12,098 (2013) (same); *Belinda R. Mori, N.P.*, 78 Fed. Reg. 36,582, 36,588 (2013) (same); *Leo A. Farmer, M.D.*, 78 Fed. Reg. 27,997, 27,999 (2013) (same); *Glenn D. Krieger, M.D.*, 76 Fed. Reg. 20,020, 20,024 (2011) (same).

Accordingly, the Agency finds that after considering the factors of 21 U.S.C. 823(g)(1), the Government satisfied its *prima facie* burden showing that Applicant's registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4); *see also* 21 U.S.C. 823(g)(1). The Agency further finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in light of the Agency's finding that Applicant violated the law, Applicant can be trusted with a registration.

V. SANCTION

Where, as here, the Government has met the burden of showing that Applicant's proposed registration is inconsistent with the public interest, the burden shifts to Applicant to show why she can be entrusted with a registration. *Morall*, 412 F.3d at 174; *Jones Total Health Care Pharmacy*, 881 F.3d at 830; *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual. *Jeffrey Stein, M.D.*, 84 Fed. Reg. 46,968, 46,972 (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 or an applicant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that they 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 an applicant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 Fed. Reg. 82,639, 82,641 (2024); *Mohammed Asgar*,

M.D., 83 Fed. Reg. 29,569, 29,573 (2018); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 830-31. The Agency also considers the need to deter similar acts by an applicant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 Fed. Reg. at 46,972-73.

Here, Applicant failed to answer the allegations contained in the OSC and did not otherwise avail herself of the opportunity to refute the Government's case. *See supra* Section I. Thus, there is no record evidence that Applicant takes responsibility, let alone unequivocal responsibility, for the misconduct. Accordingly, she has not convinced the Agency that her future controlled-substance-related actions will comply with the CSA such that she can be entrusted with the responsibilities of a registration.

Further, the interests of specific and general deterrence weigh in favor of denial. Applicant's conduct in this matter concerns the CSA's "strict requirements regarding registration" and, therefore, goes 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." *Gonzales v. Raich*, 545 U.S. at 12-14. If the Agency were to issue a registration to Applicant under these circumstances, it would send a dangerous message that compliance with the law is not essential to obtaining a registration.

In sum, Applicant has not offered any credible evidence on the record that rebuts the Government's case for denial of her application, and Applicant has not demonstrated that she can be entrusted with the responsibility of registration. Accordingly, the Agency will order the denial of Applicant's application for registration.

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the application for a DEA Certificate of Registration, Control No. W23121768C, submitted by Immacula Michel, M.D., as well as any other pending application of Immacula Michel, M.D., for registration in Florida. This Order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on September 17, 2025, by Administrator Terrance Cole. 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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