[4410-09-P]

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

Grace S. Joanita, N.P.;
Decision and Order

On February 6, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Grace S. Joanita, N.P., of Cincinnati, Ohio (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, Attachment (Attach.) F, at 1, 4. The OSC proposed the revocation of Registrant's DEA registration, No. MJ5209677, alleging that Registrant materially falsified her December 7, 2021 renewal application for registration. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).[1]

On July 5, 2023, the Government submitted an RFAA to the Administrator requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 1-3. After carefully reviewing the entire record and conducting the analysis as set forth in detail below, the Agency finds that Registrant is in default and finds that Registrant materially falsified her renewal application. Accordingly, the Agency grants the Government's RFAA and revokes Registrant's registration.

I. 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).

[1] The Government further alleged that Registrant committed acts inconsistent with the public interest. RFAAX 1, Attach. F, at 1-2 (citing 21 U.S.C. 823(g)(1)(E)). However, due to the Agency's finding that Registrant submitted a materially false application, which serves as an independent basis for sanction under 21 U.S.C. 824(a)(1), the Agency declines to analyze the public interest allegation.

The OSC notified Registrant of her right to file a written request for a hearing and an answer, and that if she failed to file such a request and answer, she would be deemed to have waived her right to a hearing and be in default.[2] RFAAX 1, Attach. F, at 2-3 (citing 21 CFR 1301.43). Registrant did not request a hearing, file an answer, or respond to the OSC in any way. RFAA, at 1-3. Accordingly, Registrant is in default. 21 CFR 1301.43(c)(1); RFAA, at 1-3.

"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]." 21 CFR 1301.43(e). Because Registrant is in default and has not moved to excuse the default, the Agency finds that Registrant has admitted to the factual allegations in the OSC. 21 CFR 1301.43(c)(1), (e), (f)(1).

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." 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), and 1301.46. RFAA, at 1-3; *see also* 21 CFR 1316.67.

II. MATERIAL FALSIFICATION

A. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted to each of the following facts.[3] On or about December 7, 2021, Registrant submitted a timely

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[2] Based on the Government's submissions in its RFAA dated July 5, 2023, the Agency finds substantial record evidence that service of the OSC on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on February 10, 2023, DI served the OSC on Registrant in-person. RFAAX 1, at 3.

In addition to DI's Declaration regarding service, the Government attached to the RFAA several substantive evidentiary exhibits that relate to the OSC allegations. Because this matter is a default, only the facts in the OSC are deemed to be admitted, and any facts found based on supplementary information submitted by the Government must be established by record evidence that meets the appropriate evidentiary standard. *See Victor Augusto Silva, M.D.*, 90 Fed. Reg. 16,002, 16,002 n.4 (2025) (finding that "a registrant's deemed admission of the factual allegations based on a default applies to the facts in the OSC only"); *see also Hayriye Gok, M.D.*, 90 Fed. Reg. 30,266, 30,266 n.2 (2025).

[3] According to the Controlled Substances Act (CSA), "[f]indings of fact by the [DEA Administrator], if supported by substantial evidence, shall be conclusive." 21 U.S.C. 877. Here, where Registrant is found to be in default, all

renewal application for her DEA registration, No. MJ5209677. RFAAX 1, Attach. F, at 1. The renewal application requested information regarding Registrant's fee exemption status. *Id*. at 1-2. Specifically, the application requested the name, title, phone number, and email address of a certifying official, and the name of a fee exempt institution. *Id*. at 2. Registrant responded to the fee exemption prompts, and provided the name of a certifying official for whom she had not worked since November 20, 2019. *Id*. Based on the information Registrant provided in response to the fee exemption prompts, her registration was granted "fee exempt" status and she therefore did not pay the required fee to renew her registration. *Id*. In December 2021, January 2022, and August 2022, DEA provided Registrant opportunities to pay the required registration fee and fill out a Change of DEA Fee Exemption Status form. *Id*. At the time the OSC was issued, Registrant had not paid the required fee or filled out the Change of DEA Fee Exemption Status form. *Id*.

B. Discussion

A DEA registration may be denied, suspended, or revoked upon a finding that the applicant or registrant materially falsified any application filed pursuant to or required by the Controlled Substances Act (CSA). 21 U.S.C. 824(a)(1).[4] To present a *prima facie* case for material falsification, the Government's record evidence must show (1) the submission of an application, (2) containing a false statement and/or omitting information that the application requires, (3) when the submitter knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure, and (4) the false statement and/or required but omitted information is material, that is, it "connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] 'shall' consider"

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the factual allegations in the OSC are deemed to be admitted. These uncontested and deemed admitted facts constitute evidence that exceeds the "substantial evidence" standard of 21 U.S.C. 877; it is unrebutted evidence.

[4] A statutory basis to deny an application pursuant to section 823 is also a basis to revoke or suspend a registration pursuant to section 824, and vice versa, because doing "otherwise would mean that all applications would have to be granted only to be revoked the next day . . . ." *Robert Wayne Locklear, M.D.*, 86 Fed. Reg. 33,738, 33,744-45 (2021) (collecting cases).

The Supreme Court's decision in *Kungys v. United States*, 485 U.S. 759 (1988), and its progeny, guide the Agency's implementation of these CSA provisions.

when analyzing "whether issuing a registration 'would be inconsistent with the public interest.'" *Frank Joseph Stirlacci, M.D.*, 85 Fed. Reg. 45,229, 45,238 (2020) (citing 21 U.S.C. 823 and *Kungys*, 485 U.S. at 771); *see also Sasha Melissa Ikramelahai*, 90 Fed. Reg. 32,017, 32,019 (2025); *Michael Bouknight*, 90 Fed. Reg. 31,247, 31,249 (2025).

Regarding materiality, *Kungys* holds that a statement is material if it is "predictably capable of affecting, *i.e.*, had a natural tendency to affect, the [Agency's] official decision," or stated differently, "had a natural tendency to influence the decision." *Kungys*, 485 U.S. at 771-72. As already discussed, materiality, for the purposes of the CSA, is tied to the factors that the Administrator "shall" consider when determining whether issuance of a registration "would be inconsistent with the public interest." 21 U.S.C. 823; *Kungys*, 485 U.S. at 771-72; *Stirlacci*, 85 Fed. Reg. at 45,234, 45,238.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. The Government must establish material falsification with record evidence that is clear, unequivocal, and convincing. *Kungys*, 485 U.S. at 772; *Stirlacci*, 85 Fed. Reg. at 45,230-39. Here, the Agency finds that the Government's clear, unequivocal, and convincing record evidence presents a *prima facie* case that Registrant submitted a materially false application. 21 U.S.C. 823, 824(a)(1).

As the Agency finds above, Registrant submitted a renewal application for DEA registration and the application requested information regarding exemption from paying the required fee. RFAAX 1, Attach. F, at 2; *see also* 21 CFR 1301.13(e) (setting forth the fee schedule); 21 CFR 1301.21 (setting forth the conditions for fee exemption). Registrant responded to the fee exemption prompts and provided employment information—specifically, the name of a certifying official—that was false at the time she submitted her renewal application, because she had not worked for that certifying official in over two years. RFAAX 1, Attach. F, at 2. By responding to the fee exemption prompts, Registrant falsely represented that she was entitled to fee exemption. *Id*. In other words, on her renewal application, Registrant

claimed to meet the regulatory requirements for a fee exemption by representing that she worked for a certifying official for whom she did not work for at the time, and she knew or should have known that she did not work for the certifying official when she submitted her application. *Id*.; *see also Ikramelahai*, 90 Fed. Reg. at 32,020 (finding registrant created the false impression that she possessed a state license when, in fact, it belonged to a different practitioner). Thus, Registrant's renewal application contained false statements.

In addition, the false statements were material. Specifically, Registrant's falsities are connected to public interest factor D, under which DEA considers an applicant's compliance or non-compliance with Federal laws relating to controlled substances. 21 U.S.C. 823(g)(1)(D). DEA's registration and renewal process are governed by the CSA and its implementing regulations—in other words, Federal laws which relate to controlled substances. In applying for a DEA registration or renewing a DEA registration, an applicant or registrant must comply with Federal laws that govern the issuance and renewal of controlled substance registrations. *See, e.g.*, 21 U.S.C. 821 (authorizing the Attorney General to promulgate regulations and charge fees relating to the registration and dispensing of controlled substances); 21 U.S.C. 822(a)(2) ("Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him."); 21 U.S.C. 823(g)(1) (setting forth the factors that the Attorney General must consider when determining whether to grant or deny a registration); 21 CFR 1301.13 (establishing application requirements, including registration fees tied to specific regulated activities); 21 CFR 1301.21 (setting forth conditions for fee exemption); *Gonzales v. Raich*, 545 U.S. 1, 14 (2005) ("The CSA and its implementing regulations set forth strict requirements regarding registration . . . ."). Thus, evaluating an applicant's or registrant's compliance with the

Federal laws that govern registration and renewal, including DEA's fee schedule and fee exemptions, is appropriately considered under factor D.[5] 21 U.S.C. 823(g)(1)(D).

Accordingly, making a false statement regarding entitlement to fee exemption has a natural tendency to influence the Agency's decision regarding whether issuance of a registration "would be inconsistent with the public interest." 21 U.S.C. 823; *Kungys*, 485 U.S. at 771-72; *Stirlacci*, 85 Fed. Reg. at 45,234, 45,238; RFAAX 1, Attach. F, at 1-2. Therefore, the falsities in Registrant's application were "predictably capable of affecting" DEA's decision to renew her registration, and therefore the Agency finds that they were material. *Kungys*, 485 U.S. at 771-72.

In sum, the Agency finds clear, unequivocal, and convincing record evidence, based on Registrant's admissions, that she submitted a materially false renewal application for registration. 21 U.S.C. 824(a)(1); 21 CFR 1301.43(e).

As a result of this established violation, the Agency finds that the Government has established a *prima facie* case for sanction, that Registrant did not rebut that *prima facie* case, and that there is clear, unequivocal, and convincing record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 824(a)(1).

C. Sanction

Where, as here, the Government has presented a *prima facie* case showing that Registrant submitted a materially false application for registration renewal, the burden shifts to Registrant to show why she can be trusted with a registration. *Morall v. Drug Enf't Admin*., 412 F.3d 165, 181 (D.C. Cir. 2005); *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 Fed. Reg. 18,882, 18,904 (2018). The issue of trust is a fact-dependent determination based on the circumstances presented by the individual practitioner. *Jeffrey Stein, M.D.*, 84 Fed. Reg. 46,968, 46,972 (2019); *see also Jones*

[5] To be clear, the Agency is not finding that Registrant violated the above-referenced portions of the CSA or its implementing regulations. This information is presented to give context to the materiality of Registrant's falsification. The Agency's only finding against Registrant is that she materially falsified a renewal application which is grounds for revocation under 21 U.S.C. 824(a)(1).

Total Health Care Pharmacy, 881 F.3d at 833. Historically, the Agency has considered acceptance of responsibility, egregiousness, and deterrence when making this assessment.

Specifically, the Agency requires the practitioner to accept responsibility for his or her violation. *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). Acceptance of responsibility must be unequivocal. *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. In addition, the Agency considers the egregiousness and extent of the misconduct in determining the appropriate sanction. *Jones Total Health Care Pharmacy*, 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by Registrant, by current registrants, and by future applicants for registration. *Stein*, 84 Fed. Reg. at 46,972-73.

Here, Registrant did not timely request a hearing, or timely or properly answer the allegations, and was therefore deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1-3. 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 herself of the opportunity to refute the Government's case. As such, Registrant has not accepted responsibility for the proven violations, has made no representations regarding her future compliance with the CSA, and has not made any demonstration that she can be trusted with registration.

Moreover, the evidence presented by the Government shows that Registrant provided false information regarding her fee exempt status. Providing false information as part of an application process for controlled substance privileges governed by Federal law calls into question Registrant's honesty, trustworthiness, and ability or willingness to comply with the laws governing controlled substances. To permit Registrant to maintain a registration under these circumstances would send a dangerous message that DEA does not expect compliance with its registration requirements and that the registration fees required by statute and regulation can be

circumvented without consequence by making false statements. Registrant and the regulated community must be on notice that DEA's registration and renewal process, to include the required fees, is governed by Federal law, that DEA will strictly enforce those Federal laws, and that DEA expects applicants and registrants to adhere to those Federal laws.

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. MJ5209677 issued to Grace S. Joanita, N.P. 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 Grace S. Joanita, N.P., to renew or modify this registration, as well as any other pending application of Grace S. Joanita, N.P., for additional registration in Ohio. This Order is effective **[INSERT DATE THIRTY DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on October 1, 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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