

revoke DEA Certificate of Registration No. FA4195459 issued to Ajumobi Agu, M.D. 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 Ajumobi Agu, M.D., to renew or modify this registration, as well as any other pending application of Ajumobi Agu, M.D., for additional registration in Nevada. This Order is effective May 16, 2025.

### Signing Authority

This document of the Drug Enforcement Administration was signed on April 10, 2025, by Acting Administrator Derek Maltz. 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

#### Lona Bibbs-Walker, D.D.S.; Decision and Order

#### I. Introduction

On May 13, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registrations (OSC/ISO) to Lona Bibbs-Walker, D.D.S., of Fayetteville, Georgia (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Registrant of the immediate suspension of her DEA Certificates of Registration, Nos. FB3395806 and FB9305891, 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.* (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

The OSC/ISO alleged that from May 19, 2020, through February 16, 2024, Registrant failed to maintain adequate records relating to her handling of controlled substances. *Id.* The OSC/ISO also alleged that Registrant was unable to account for hundreds of dosage units of highly diverted controlled substances. *Id.* Finally, the OSC/ISO alleged that Registrant does not have state authority to practice dentistry since on or about March 5, 2024. *Id.* The OSC/ISO alleged that Registrant's above-described misconduct violated both the implementing regulations of the Controlled Substances Act (CSA) and Georgia state law. *Id.* at 2.

The OSC/ISO notified Registrant of her right to file with DEA a written request for hearing and an answer, 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. RFAAX 2, at 5 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.<sup>1</sup> "A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC/ISO]." 21 CFR 1301.43(e); *see also* RFAAX 2, at 5 (providing notice to Registrant).

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." *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(a), (c), (f), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

#### II. Lack of State Authority

##### A. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are deemed admitted. Accordingly, Registrant admits that on March 5, 2024, the Georgia Board of Dentistry revoked Registrant's authority to practice

dentistry in Georgia. *Id.* at 4. According to Georgia online records, of which the Agency takes official notice,<sup>2</sup> Registrant's authority to practice dentistry in Georgia remains revoked. Georgia Department of Community Health License Verification, <https://gadch.mylicense.com/verification> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice dentistry in Georgia, the state in which she is registered with DEA.<sup>3</sup>

##### B. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) ("The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. § 802(21)."). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th

<sup>2</sup> Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

<sup>3</sup> Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." The material fact here is that Registrant, as of the date of this decision, is not licensed to practice dentistry in Georgia. Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to DEA Office of the Administrator, Drug Enforcement Administration at [dea.addo.attorneys@dea.gov](mailto:dea.addo.attorneys@dea.gov).

<sup>1</sup> Based on the Government's submissions in its RFAA dated August 20, 2024, the Agency finds that service of the OSC/ISO on Registrant was adequate. Specifically, the included Declaration from a DEA Diversion Investigator (DI) indicates that on May 14, 2024, the DI and other DEA personnel traveled to Registrant's registered address and personally served the OSC/ISO on an individual authorized by Registrant's attorney to accept service on Registrant's behalf. RFAAX 2, at 2. Further, on the same date, the DI served a copy of the OSC/ISO via email to Registrant's registered email address, with Registrant's attorney courtesy copied. *Id.*

Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27616, 27617 (1978).<sup>4</sup>

According to Georgia statute, “dispense” means “to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery . . . .” Ga. Code Ann. section 16–13–21(9) (2024). Further, a “practitioner” means a “physician . . . or other person licensed, registered, or otherwise authorized under the laws of [Georgia] to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in [Georgia].” *Id.* section 16–13–21(23)(A).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice dentistry in Georgia, *supra* II.A. As discussed, an individual must be a licensed practitioner to dispense a controlled substance in Georgia. Thus, because Registrant lacks authority to practice dentistry in Georgia and, therefore, is not authorized to handle controlled substances in Georgia, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that the Registrant’s registration be revoked.

### III. Public Interest

#### A. Applicable Law

As discussed above, the OSC/ISO alleges that Registrant violated provisions of the Controlled Substances Act (CSA) and its implementing regulations. As the Supreme Court stated in *Gonzales v. Raich*, “the main objectives of the CSA were to conquer drug abuse and to control the legitimate

and illegitimate traffic in controlled substances. . . . To effectuate these goals, Congress devised a closed regulatory system making it unlawful to . . . dispense[] or possess any controlled substance except in a manner authorized by the CSA.” 545 U.S. 1, at 12–13 (2005). In maintaining this closed regulatory system, “[t]he CSA and its implementing regulations set forth strict requirements regarding registration, . . . drug security, and recordkeeping.” *Id.* at 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.” *Id.*

*Inadequate Recordkeeping and Missing Controlled Substances* (21 CFR 1304.04(a), 1304.11(a)–(c), 1304.21(a) and Ga. Comp. R. & Regs. section 480–28–.04(4), (5)(a)–(b))

The OSC/ISO alleges that from May 19, 2020, through February 16, 2024, Registrant failed to maintain adequate records relating to her handling of controlled substances. RFAAX 1, at 1. The OSC/ISO also alleges that Registrant was unable to account for hundreds of dosage units of highly diverted controlled substances. *Id.*

Under the CSA, registrants are required to keep current and accurate records of all controlled substances handled. 21 CFR 1304.21(a). Further, registrants are required to take a complete and accurate inventory of all controlled substances on hand from the date they first engage in the dispensing of controlled substances and, thereafter, must take biennial inventories; such inventories must be kept for at least two years from the date of their creation. *Id.* §§ 1304.04(a), 1304.11(a)–(c).

Similarly, Georgia regulations require that practitioners maintain prescription records for two years from the date the prescriptions are filled, and such records must be kept available for inspection. Ga. Comp. R. & Regs. section 480–28–.04(4). Further, Georgia regulations require that practitioners maintain records of “all controlled substance drugs received and disposed of” as well as maintain an inventory of all controlled substances, which must be taken biennially. *Id.* section 480–28–.04(5)(a)–(b).

#### B. Findings of Fact

Registrant is deemed to have admitted that from May 19, 2020, through at least February 16, 2024, she failed to

maintain proper records regarding her inventory, purchasing, and dispensing of controlled substances. RFAAX 1, at 3. Further, Registrant is deemed to have admitted that she failed to adequately maintain an initial or biennial inventory of controlled substances. *Id.* Finally, Registrant is deemed to have admitted that between May 19, 2020, through at least February 16, 2024, she was unable to account for at least the following controlled substances: 200 dosage units of hydrocodone acetaminophen (a Schedule II opioid) 5/325 mg; 100 dosage units of hydrocodone acetaminophen 7.5/325 mg; 500 dosage units of hydrocodone acetaminophen 10/325 mg; 600 dosage units of oxycodone (a Schedule II opioid) 10 mg; 100 dosage units of oxycodone 15 mg; 700 dosage units of oxycodone 30 mg; and 118 bottles of promethazine with Codeine (a Schedule V opioid), with each bottle typically including 473 to 480 ml. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant failed to maintain proper records regarding her purchasing and dispensing of controlled substances, and her initial or biennial inventory of controlled substances. RFAAX 1, at 3. These failures resulted in Registrant being unable to account for hundreds of dosage units of controlled substances.

#### C. Discussion

##### *The Controlled Substances Act’s Public Interest Factors*

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).<sup>5</sup>

The five factors are considered in the disjunctive. *Gonzales v. Oregon*, 546 U.S. 243, 292–93 (2006) (Scalia, J.,

<sup>5</sup> 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.

<sup>4</sup> This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner’s registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper, M.D.*, 76 FR 71371–72; *Sheran Arden Yeats, M.D.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.*, 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton, M.D.*, 43 FR 27617.

dissenting) (“It is well established that these factors are to be considered in the disjunctive,” citing *In 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 185 n.2; *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

According to Agency decisions, the Agency “may rely on any one or a combination of factors and may give each factor the weight [it] deems appropriate in determining whether” to revoke a registration. *Id.*; see also *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi v. Drug Enf’t Admin.*, 841 F.3d 707, 711 (6th Cir. 2016)); *MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. U. S. Drug Enf’t Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enf’t Admin.*, 419 F.3d 477, 482 (6th Cir. 2005).

Moreover, while the Agency is required to consider each of the factors, it “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); see also *Hoxie*, 419 F.3d at 482. “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, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

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 regarding Registrant’s violations of the CSA’s implementing regulations is confined to Factors B and D. See RFAAX 1, at 3–4. Moreover, the Government has the burden of proof in this proceeding. 5 U.S.C.A. 556(d); 21 CFR 1301.44.

Here, the Agency finds that the Government’s evidence satisfies its *prima facie* burden of showing that Registrant’s continued registration would be “inconsistent with the public interest.”

21 U.S.C. 823(g)(1)

#### *Factors B and/or D—Registrant Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances*

Evidence is considered under Public Interest Factors B and D when it reflects compliance or non-compliance with federal and local laws related to controlled substances and experience dispensing controlled substances. 21 U.S.C. 823(g)(1)(B) and (D); see also *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). Here, as found above, Registrant is deemed to have admitted and the Agency finds that from May 19, 2020, through February 16, 2024, Registrant failed to maintain adequate records relating to her handling of controlled substances and was unable to account for hundreds of dosage units of controlled substances. RFAAX 1, at 1.

As such, the Agency finds substantial record evidence that Registrant violated 21 CFR 1304.04(a), 1304.11(a)–(c), 1304.21(a) and Ga. Comp. R. & Regs. section 480–28–.04(4), (5)(a)–(b). After weighing Factors B and D, the Agency further finds that Registrant’s continued registration is inconsistent with the public interest. 21 U.S.C. 823(g)(1). Accordingly, the Agency finds that the Government established a *prima facie* case, that Registrant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Registrant’s registration. 21 U.S.C. 823(g)(1).

#### *D. Sanction*

Here, the Government has met its *prima facie* burden of showing that Registrant’s continued registration is inconsistent with the public interest due to her numerous violations pertaining to controlled substance dispensing and recordkeeping. Accordingly, the burden shifts to Registrant to show why she can be entrusted with 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, 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 he 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 & n.4. The Agency has also considered the need to deter similar acts by the registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46972–73.

Here, Registrant failed to answer the allegations contained in the OSC/ISO and did not otherwise avail herself of the opportunity to refute the Government’s case. As such, there is no record evidence that Registrant takes responsibility, let alone unequivocal responsibility, for the founded violations, meaning, among other things, that it is not reasonable to believe that Registrant’s future controlled substance-related actions will comply with legal requirements. Accordingly, Registrant did not convince the Agency that she can be entrusted with registration.

Further, the interests of specific and general deterrence weigh in favor of revocation. Given the foundational nature of Registrant’s violations, 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.

#### *E. Conclusion*

Accordingly, I shall order the sanction the Government requested, 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) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificates of Registration Nos. FB3395806 and FB9305891 issued to Lona Bibbs-Walker, D.D.S. 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 Lona Bibbs-Walker, D.D.S., to renew or modify the named registrations, as well as any other pending application of Lona Bibbs-Walker, D.D.S., for

additional registration in Georgia. This Order is effective May 16, 2025.

### Signing Authority

This document of the Drug Enforcement Administration was signed on April 10, 2025, by Acting Administrator Derek Maltz. 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. 2025-06427 Filed 4-15-25; 8:45 am]

**BILLING CODE 4410-09-P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Victor Augusto Silva, M.D.; Order

On February 22, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Victor Augusto Silva, M.D., of Tampa, Florida (Respondent). Request for Final Agency Action (RFAA), at 1; RFAA Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, No. FS3590266, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes "an imminent danger to the public health or safety." RFAAX 1, at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, No. FS3590266, alleging that Respondent's registration is inconsistent with the public interest. *Id.*

More specifically, the OSC/ISO alleged that Respondent allowed an unauthorized person to use his registration to prescribe controlled substances in violation of federal regulations and Florida law. RFAAX 1, at 1–3. On April 18, 2024, the Government submitted an RFAA to the Administrator requesting that the Agency issue a default final order revoking Respondent's registration. RFAA, at 1.

As a preliminary matter, this decision addresses whether or not Respondent is in default and finds that he is. Thereafter, the decision makes specific factual findings on the alleged violations as set forth in the OSC. Next, the decision considers whether Respondent's continued registration is inconsistent with the public interest by evaluating the found violations in the context of the public interest factors. Where, as here, the Agency determines that Respondent's continued registration is inconsistent with the public interest, the Respondent is then given an opportunity to argue for mitigation of the sanction by establishing that he can be trusted with a registration. 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 Respondent'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). Unless excused, a default constitutes "an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Here, the OSC/ISO notified Respondent of his right to file with DEA a written request for a hearing and informed him that if he failed to file a hearing request or an answer, he would be deemed to have waived his right to a hearing and be in default. RFAAX 1, at 4. Respondent requested a hearing on April 2, 2024.<sup>1</sup> RFAAX 3, at 3. On April 3, 2024, the Government filed proof that it had served the OSC/ISO on Respondent on February 23, 2024. Government's Notice of Service, Exhibit A, at 1. Administrative Law Judge (ALJ) Teresa A. Wallbaum provided a briefing schedule for any Government motions related to the timeliness of Respondent's hearing request with an opportunity for Respondent to file a response addressing his reasons for failing to file the request for a hearing within the time

provided by the OSC/ISO. Briefing Order Regarding Timeliness of Request for Hearing, at 1–2. Respondent's response to any Government motion was due on April 17, 2024. *Id.*, at 3. On April 4, 2024, the ALJ reminded Respondent of the filing deadline for his response. Order Regarding Status Conference, at 2. On April 10, 2024, the Government filed a motion to terminate proceedings.<sup>2</sup> RFAAX 3, at 1–2; Government's Motion to Terminate Proceedings, at 1. When Respondent failed to file a response by the deadline, the ALJ issued an order on April 18, 2024, granting the Government's motion and terminating the administrative proceedings. RFAAX 3, at 2, 4.

The Government's RFAA to the Administrator requested that the Agency issue a final order revoking Respondent's registration on the basis that his continued registration is inconsistent with the public interest. RFAA, at 1 (citing 21 U.S.C. 824(a)(4)). The Government requested final agency action "pursuant to 21 CFR 1301.43(c) and (f) . . . , because Respondent has neither timely requested a hearing, nor provided answers for the [OSC/ISO]." *Id.*

Under these facts, the Agency finds that the ALJ's termination of the proceedings—where Respondent failed to timely file a request for a hearing and an answer and did not demonstrate good cause for the failures—was appropriate.<sup>3</sup> See RFAAX 3, at 3–4 (citing 21 CFR 1301.43(a) & (c)(2)–(f)(1), 1316.47). Thus, the Agency finds that that Respondent is in default and has admitted to the factual allegations in the OSC/ISO.<sup>4</sup> 21 CFR 1301.43(e).

<sup>2</sup> The Government submitted the motion after 5:00 p.m. on April 9, 2024; the ALJ deemed it filed the following business day. RFAAX 3, at 2 n.3.

<sup>3</sup> Subsequent filings by Respondent, even if viewed as motions to excuse the default, also fail to establish good cause for the default. 21 CFR 1301.43(f)(2). Both the OSC/ISO and the Order for Prehearing Statements provided notice of the requirement to timely file an answer. Order for Prehearing Statements, at 2; RFAAX 1, at 4.

<sup>4</sup> The Government's RFAA notes that certain facts alleged in the OSC/ISO are incorrect and seeks to correct them. RFAA, at 3 n.2. According to the Government, the timeframe alleged in the OSC of "June 2023 to December 2023" should be corrected to "June 2022, to December 2023." *Id.* Thus, the Government seeks to expand the timeframe of one of the two OSC/ISO paragraphs (paragraph five) containing the details of the allegations of Respondent's unlawful prescribing of controlled substances. RFAAX 1, at 3. Although the Government may propose corrections to an OSC during a hearing process, *Judson J. Somerville, M.D.*, 82 FR 21408, 21408 n.1 (2017) (correcting registration number), a registrant's deemed "admission of the factual allegations" based on a default applies to the facts in the OSC only. 21 CFR 1301.43(e) ("A default, unless excused, shall be deemed to constitute . . . an admission of the factual allegations of the [OSC]."). Accordingly, the

<sup>1</sup> Respondent submitted the hearing request electronically after 5:00 p.m. on April 1, 2024. Briefing Order Regarding Timeliness of Request for Hearing, at 1 & n.1 (citing 21 CFR 1316.45).