EXHIBIT A

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

APR 10 2023

IN THE MATTER OF

Simfarose Pharmacy
10016 Pines Boulevard
Pembroke Pines, Florida 33024

DEA Certificate of Registration No. FS0588004

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Simfarose Pharmacy (the Pharmacy or Respondent) of the immediate suspension of Drug Enforcement Administration (DEA) Certificate of Registration (COR) No. FS0588004, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes "an imminent danger to the public health or safety." Notice is also given to afford the Pharmacy an opportunity to show cause before DEA at the DEA Hearing Facility located at 700 Army Navy Drive, 2nd Floor, Arlington, VA 22202, or at a location designated by the Administrative Law Judge, on June 13, 2023, (if Respondent requests such a hearing), as to why DEA should not revoke Respondent's registration pursuant to 21 U.S.C. § 824(a)(4), and deny any applications for renewal or modification of such registration, whether pending currently or filed at any time prior to DEA's final decision in this matter, because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(g)(1).

As detailed below, this order states DEA's basis for this Order to Show Cause and Immediate Suspension of Registration, including a ***non-exhaustive summary*** of facts and law at issue, as well as citations to laws and regulations that the Pharmacy has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia*). In order to preserve the Pharmacy's rights in this proceeding, the Pharmacy may appear in these revocation proceedings by filing a notice of appearance or request for a hearing in the manner prescribed by regulations within 30 days from the receipt of this Order.

LEGAL REQUIREMENTS

A "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. A pharmacist is only permitted to fill prescriptions "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

"DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when [s]he either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharmacy*, 78 Fed. Reg. 69,441, 69,445 (2013) (internal quotation marks and citation omitted, alternation in original). Section 1306.04(a) "expressly requires pharmacists to identify and resolve suspicions that a prescription is illegitimate." *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7331 (2018).

A violation of these regulations is a violation of federal law. *See* 21 U.S.C. § 842(a)(1) (making it unlawful to dispense controlled substances in violation of 21 U.S.C. § 829, whose scope is defined in part by 21 C.F.R. §§ 1306.04, 1306.06). Any attempt to violate these regulations is also a violation of federal law. *See* 21 U.S.C. § 846.

In addition to complying with federal statutes and regulations, the Pharmacy and its pharmacists also must comply with applicable Florida law. In particular, Florida pharmacists must "review the patient record and each new and refill prescription presented for dispensing" to identify, among other things, "[o]ver-utilization or under-utilization," "[t]herapeutic duplication," "[d]rug–drug interactions," "[i]ncorrect drug dosage or duration of drug treatment," and "[c]linical abuse/misuse." Fla. Admin. Code Ann. r. 64B16-27.810(1).

Upon recognizing any of these red flags of abuse or diversion, a Florida pharmacist "shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber." Fla. Admin. Code Ann. r. 64B16-27.810(2). Florida pharmacists must also maintain a patient record system that documents resolution of red flags. *See id.* r. 64B16-27.800.

Further, Florida pharmacists must comply with other regulations for filling controlled substance prescriptions. *See* Fla. Admin. Code Ann. r. 64B16-27.831 (requiring pharmacists, among other things, to exercise sound professional judgment and attempt to work with the patient and the prescriber to assist in determining the validity of the prescription).

A Florida pharmacy's failure to comply with Florida's prescription review requirements also constitutes a violation of the federal Controlled Substances Act. *See, e.g.*, *Trinity Pharmacy II*, 83 Fed. Reg. at 7329 ("Thus, [Florida] pharmacists violate Florida law if they fail to identify and resolve the red flags that are part of the prospective drug use review set forth in Rule 64B16-27.810. And if they knowingly fill prescriptions without resolving these red flags during this review, then they violate their corresponding responsibility under 21 CFR 1306.04(a).").

BACKGROUND

1. The Pharmacy is registered with DEA to handle controlled substances in Schedules II through V under DEA COR No. FS0588004. The Pharmacy's registered address is 10016 Pines Boulevard, Pembroke Pines, Florida 33024. The Pharmacy's COR expires by its own terms on February 28, 2026.

2. The Pharmacy's DEA COR should be revoked and any pending application should be denied because the Pharmacy has committed such acts as would render its registration inconsistent with the public interest under the Controlled Substances Act. *See* 21 U.S.C. §§ 823(g)(1), 824(a)(4). The Pharmacy repeatedly dispensed prescriptions in violation of the minimum practice standards that govern pharmacy practice in Florida.

3. Specifically, from on or about January 12, 2016, until at least October 21, 2022, the Pharmacy repeatedly filled prescriptions for Schedule II through V controlled substances that contained multiple red flags of abuse or diversion without addressing or resolving those red flags, and the decisions of Respondent to fill those prescriptions despite unresolved red flags, were in violation of both federal and Florida law, including 21 C.F.R. §§ 1306.04(a), 1306.06; and Fla. Admin. Code Ann. r. 64B16-27.810.

4. DEA's investigation found that from on or about January 12, 2016, until at least October 21, 2022, the Pharmacy engaged in conduct that demonstrates negative experience in dispensing with respect to controlled substances, *see* 21 U.S.C. § 823(g)(1)(B); and failed to comply with applicable State, Federal, or local laws relating to controlled substances. *See* 21 U.S.C. § 823(g)(1)(D). Respondent's decisions to fill prescriptions despite unresolved red flags were in violation of law. *See Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7331 (2018); *JM Pharmacy Grp., Inc., d/b/a Farmacia Nueva & Best Pharma Corp.*, 80 Fed. Reg. 28,667, 28,670 (2015).

LONG-TERM USE OF IMMEDIATE-RELEASE OPIOIDS, THERAPEUTIC DUPLICATION, AND HIGH OPIOID DOSAGES

DEA has found that extended use of immediate-release opioids is a red flag of abuse or diversion because extended-release opioids are generally more appropriate for treatment of chronic pain. *See Pharmacy 4 Less*, 86 Fed. Reg. 54,550, 54,575 (2021). Similarly, filling prescriptions for a patient for multiple controlled substances that have essentially the same effect on the patient's body, such as combinations of immediate-release opioids, is known as "therapeutic duplication" and is another well-known red flag of abuse or diversion that must be addressed and resolved before dispensing a prescription. *See Trinity Pharmacy II*, 83 Fed. Reg. at 7332 (holding that therapeutically duplicative prescriptions raise a strong suspicion of diversion and failing to resolve that suspicion violates 21 C.F.R § 1306.04).

Likewise, high dosages of opioids, or combinations of opioids at high dosages, often can be a red flag because high dosages can significantly increase a patient's risk of overdose and death. *See, e.g., George Pharmacy, Inc.*, 87 Fed. Reg. 21,145, 21,152 (2002) (finding that

"prescriptions for high dosages and dangerous combinations of controlled substances" are among the basis for concluding that registrant pharmacy violated "its corresponding responsibility under 21 CFR 1306.04(a)"). Prescribing a controlled substance opioid at "the highest strength available" is a red flag. *See Gulf Med Pharmacy*, 86 Fed. Reg. 72,694, 72,705 (2021).

Florida law requires a pharmacist to identify and address all of these red flags *See* Fla. Admin. Code Ann. r. 64B16-27.810(1) & (2) (requiring pharmacists to identify and resolve red flags of, among other things, therapeutic duplication, over-utilization or under-utilization, and duration of drug treatment).

5. The Pharmacy repeatedly failed to appropriately identify and resolve red flags associated with opioid prescriptions it filled for multiple patients. The Pharmacy frequently filled immediate-release opioid prescriptions for its patients on a regular basis over a significant period of time – often at the highest strength available and/or in a therapeutically duplicative combination with other immediate-release opioids. This red flag is unresolvable after two to three months of prescribing. Some of these prescriptions were at high morphine milligram equivalents (MMEs). Examples include, but are not limited to, the following:

   a. Between November 6, 2019, and October 21, 2022, often on a monthly basis, the Pharmacy filled prescriptions for Patient C.S. for oxycodone 30 mg (an immediate-release Schedule II opioid). During this time period, the Pharmacy frequently also filled concurrent prescriptions for oxycodone/acetaminophen 10/325 mg (also an immediate-release Schedule II opioid). These prescriptions provided Patient C.S. with approximately 210 MME/day.

   b. Between May 21, 2021, and October 21, 2022, often on a monthly basis, the Pharmacy filled prescriptions for oxycodone 30 mg for Patient R.S. These prescriptions provided Patient R.S. with approximately 180 MME/day.

   c. Between April 12, 2021, and October 21, 2022, often on a monthly basis, the Pharmacy filled prescriptions for oxycodone 30mg or oxycodone 20 mg for Patient K.F. During this time period, the Pharmacy frequently also filled prescriptions for 10 to 15 patches of fentanyl (a Schedule II opioid). These prescriptions provided Patient K.F. with between approximately 282-630 MME/day.

   d. Between April 20, 2021, and October 20, 2022, often on a monthly basis, the Pharmacy filled prescriptions for oxycodone 30 mg for Patient J.R. These prescriptions provided Patient J.R. with between approximately 157-180 MME/day.

   e. Between May 26, 2021, and October 13, 2022, often on a monthly basis, the Pharmacy filled prescriptions for hydromorphone 8 mg (an immediate-release Schedule II opioid) for Patient H.S. These prescriptions provided Patient H.S. between approximately 128-137 MME/day.

f. Between June 19, 2020, and August 25, 2022, often on a monthly basis, the Pharmacy filled prescriptions for oxycodone 30 mg for Patient A.W. These prescriptions provided Patient A.W. with approximately 270 MME/day.

g. Between October 29, 2019, and May 31, 2022, often on a monthly basis, the Pharmacy filled prescriptions for oxycodone 30 mg or oxycodone 20 mg for Patient Da.B. These prescriptions provided Patient Da.B. with between approximately 180-270 MME/day.

h. Between September 25, 2020, and February 4, 2022, often on a monthly basis, the Pharmacy filled prescriptions for Patient M.S. for oxycodone 30 mg. During this time period, the Pharmacy frequently also filled concurrent prescriptions for tramadol 50 mg (an immediate-release Schedule IV opioid). These prescriptions provided Patient M.S. with between approximately 210-300 MME/day.

i. Between April 14, 2020, and July 14, 2021, often on a monthly basis, the Pharmacy filled prescriptions for oxycodone 30 mg for Patient D.E. Between August 15, 2021, and September 29, 2022, often on a monthly basis, the Pharmacy filled prescriptions for hydromorphone 8mg for Patient D.E. These prescriptions provided Patient D.E. with between approximately 180-270 MME/day.

j. Between July 9, 2019, and April 8, 2020, and between November 1, 2021, and September 27, 2022, often on a monthly basis, the Pharmacy filled concurrent prescriptions for Patient De.B. for oxycodone 30 mg and oxycodone/acetaminophen 10/325 mg. These prescriptions provided Patient De.B. with approximately 105-225 MME/day.

6. The Pharmacy's decision to fill these prescriptions despite these unresolved red flags was in violation of both federal and Florida law, including 21 C.F.R. §§ 1306.04(a) & 1306.06; and Fla. Admin. Code Ann. r. 64B16-27.810 & 64B16-27.831.

DRUG COCKTAILS

DEA has long recognized the prescribing of so-called "drug cocktails" as being a "red flag" of abuse or diversion. *See, e.g., Jones Total Health Care Pharmacy, LLC*, 81 Fed. Reg. 79,188, 79,189 (2016). Drug cocktails are combinations of controlled substances that are widely known to be abused or diverted, and that significantly increase a patient's risk of serious medical consequences. These risks require a pharmacist to carefully review whether the prescriptions were issued for a legitimate medical purpose.

Common drug cocktails include the combination of an opioid and benzodiazepine, an opioid and stimulant, or an opioid and muscle relaxant. DEA has long held that these cocktails are highly abused and associated with diversion. *See, e.g., Craig Rosenblum, M.D.*, 87 Fed. Reg. 21,181, 21,189 (2022) (noting that investigators are trained to look for combinations to include opioids with benzodiazepines, stimulants, and muscle relaxers); *Jacobo Dreszer, M.D.*, 76 Fed. Reg. 19,386, 19,389 (2011) (noting that "[w]hen opioids and benzodiazepines are used in

combination, the potential for [a] drug overdose and death is increased" (internal quotations omitted, alteration in original)). In particular, DEA has long held that a combination of an opioid, a benzodiazepine, and a muscle relaxant – commonly referred to by illicit drug seekers as a "Trinity" cocktail – is highly abused. *See, e.g.*, *Paul H. Volkman*, 73 Fed. Reg. 30,630, 30,637 (2008) (describing the Trinity as an example of a drug cocktail).

7. The Pharmacy repeatedly dispensed drug cocktails without addressing or resolving this red flag. Examples include:

   a. On or about May 12, 2021, through October 14, 2022, the Pharmacy filled prescriptions for Patient M.S. of a drug cocktail consisting of oxycodone and alprazolam (a Schedule IV benzodiazepine).

   b. On or about June 7, 2021, through October 12, 2022, the Pharmacy filled prescriptions for Patient Da.B. of a drug cocktail consisting of oxycodone and carisoprodol (a Schedule IV muscle relaxer).

   c. On or about June 19, 2020, through August 25, 2022, the Pharmacy filled prescriptions for Patient A.W. of a drug cocktail consisting of oxycodone, carisoprodol, and diazepam (a Schedule IV benzodiazepine).

   d. On or about July 23, 2021, through August 17, 2022, the Pharmacy filled prescriptions for Patient H.S. of a drug cocktail consisting of hydromorphone and alprazolam.

   e. On or about November 6, 2019, through July 27, 2021, the Pharmacy filled prescriptions for Patient C.S. of a drug cocktail consisting of oxycodone, oxycodone/acetaminophen, and either cyclobenzaprine (a non-controlled muscle relaxer) or tizanidine (a non-controlled muscle relaxer).

   f. On or about September 19, 2019, through February 9, 2021, the Pharmacy filled prescriptions for Patient K.F. of a drug cocktail consisting of oxycodone and alprazolam.

   g. On or about May 30, 2017, through May 14, 2018, the Pharmacy filled prescriptions for Patient D.E. of a drug cocktail consisting of oxycodone, alprazolam, and the muscle relaxer tizanidine.

8. The Pharmacy's decision to fill these prescriptions despite these unresolved red flags was in violation of both federal and Florida law, including 21 C.F.R. §§ 1306.04(a) and 1306.06; and Fla. Admin. Code Ann. r. 64B16-27.810 & 64B16-27.831.

CASH PAYMENTS AND HIGH PRICES

Cash payments are a common red flag of abuse and diversion. When a patient pays for controlled substances with cash, it permits a patient to avoid scrutiny associated with the use of insurance as part of the payment process; insurance companies will often decline to pay for suspicious controlled substance prescriptions that may be related to drug abuse and diversion.

DEA and Florida have recognized that cash payment for controlled substance prescriptions is a red flag of abuse and diversion. *See, e.g., E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,164 (2010) (describing cash payments for controlled substances as a red flag of abuse and diversion because "[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect" (internal quotation marks omitted)).

Cash payments are especially suspicious when the patient is willing to pay significantly more for the controlled substance than the amount the same controlled substance is being sold for at other local pharmacies. This is because a patient typically would not pay these high prices for a medication that can be purchased elsewhere for a fraction of that amount. *See Pharmacy 4 Less*, 86 Fed. Reg. 54,550, 54,571 (2021) (finding respondent's patients/customers paying unusually high prices triggered a red flag that respondent failed to resolve); *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10,876, 10,897 (2018) ("[T]hat Respondent charged exorbitantly high prices for controlled substance prescriptions is further proof that Respondent knew or subjectively believed that there was a high probability that its customers were either abusing or diverting those controlled substances.").

9. Many of the Pharmacy's above-referenced patients paid prices significantly higher than the market norm for their prescriptions, and did so in cash. The Pharmacy failed to appropriately resolve this red flag. Specific examples of patients paying the Pharmacy in cash include:

    a. Patient M.S. paid in cash for oxycodone. Patient M.S. paid prices from $880.00 for 110 tablets to $960.00 for 120 tablets ($8.00 per pill) of oxycodone starting on or about January 14, 2016, to at least December 14, 2021, which is well above the market price.

    b. Patient C.S. paid in cash for oxycodone. Patient C.S. paid $960.00 for 120 tablets ($8.00 per pill) of oxycodone starting on or about January 18, 2016, to at least December 7, 2021, which is well above the market price.

    c. Patient A.W. paid in cash for oxycodone. Patient A.W. paid prices from $360.00 for 60 tablets to $480.00 for 60 tablets ($6.00 to $8.00 per pill) of oxycodone starting on or about September 23, 2016, to at least December 1, 2021, which is well above the market price.

    d. Patient De.B. paid in cash for oxycodone. Patient De.B. paid $960.00 for 120 tablets ($8.00 per pill) of oxycodone starting on or about January 12, 2016, to at least November 30, 2021, which is well above the market price.

    e. Patient H.S. paid in cash for hydromorphone. Patient H.S. paid $960.00 for 120 tablets ($8.00 per pill) of hydromorphone 8 mg starting on or about December 21, 2016, to at least December 7, 2021, which is well above the market price.

    f. Patient R.S. paid in cash for oxycodone. Patient R.S. paid $960.00 for 120 tablets ($8.00 per pill) of oxycodone starting on or about June 16, 2016, to at least July 18, 2018, which is well above the market price.

g. Patient D.E. paid in cash for oxycodone. Patient D.E. paid $960.00 for 120 tablets ($8.00 per pill) of oxycodone starting on or about October 12, 2016, to at least January 15, 2019, which is well above the market price.

10. The Pharmacy's decision to fill these prescriptions despite these unresolved red flags was in violation of both federal and Florida law, including 21 C.F.R. §§ 1306.04(a) and 1306.06 and Fla. Admin. Code Ann. r. 64B16-27.831.

LONG DISTANCES

DEA has found that traveling long distances to obtain or fill controlled substance prescriptions is a well-known red flag of abuse or diversion. *See, e.g., E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,164 (2010) (holding that "the fact that the patients were driving so far to get their prescriptions filled 'would be a major red flag to any pharmacist'").

11. The Pharmacy filled controlled substance prescriptions for patients who traveled long distances to fill prescriptions. The Pharmacy consistently failed to resolve this red flag prior to dispensing. Consequently, the Pharmacy issued these controlled substance prescriptions outside the usual course of professional practice and in violation of the minimum standard of care that governs the practice of pharmacy in Florida. Examples include, but are not limited to, the following patients:

a. Patient D.E.'s address is in Fort Lauderdale, FL. Patient D.E.'s doctor's office is located in Pompano Beach, FL, 15 miles north from D.E.'s home. D.E. traveled 26 miles southeast to the Pharmacy in Pembroke Pines, FL. Finally, D.E. traveled 11 miles northeast back home. Therefore, D.E. traveled a total of approximately 52 miles, and approximately one hour and 20 minutes each trip.

b. Patient H.S.'s address is in Plantation, FL. Patient H.S.'s doctor's office is located in North Miami Beach, FL, 20 miles south from H.S.'s home. H.S. traveled 12 miles northwest to the Pharmacy in Pembroke Pines, FL. Finally, H.S. traveled 14 miles north back home. Therefore, H.S. traveled a total of approximately 46 miles and approximately one hour and 25 minutes each trip.

c. Patient M.S.'s address is in Miami, FL. Patient M.S.'s doctor's office is located in Miami, FL, 18 miles south from M.S.'s home. M.S. traveled 25 miles northwest past M.S.'s residence to the Pharmacy in Pembroke Pines, FL. Finally, M.S traveled six miles south back home. Therefore, M.S. traveled a total of approximately 49 miles and approximately one hour and 25 minutes each trip.

d. Patient K.F.'s address is in Fort Lauderdale, FL. Patient K.F.'s doctor's office is located in Miami, FL, 39 miles south from K.F.'s home. K.F. traveled 29 miles north to the Pharmacy in Pembroke Pines, FL. Finally, K.F. traveled 8 miles northeast back home. Therefore, K.F. traveled a total of approximately 76 miles and approximately one hour and 50 minutes each trip.

12. The Pharmacy's decision to fill these prescriptions despite these unresolved red flags was in violation of both federal and Florida law, including 21 C.F.R. §§ 1306.04(a) and 1306.06 and Fla. Admin. Code Ann. r. 64B16-27.831.

EXPERT REVIEW

13. DEA retained an independent pharmacy expert who reviewed the Pharmacy's PDMP data, prescriptions, prescription profiles, medical expense reports, and patient notes and concluded that the Pharmacy repeatedly filled prescriptions without properly resolving red flags of drug abuse or diversion. The pharmacy expert concluded that from on or about January 12, 2016, until at least October 21, 2022, the Pharmacy repeatedly filled prescriptions for controlled substances in violation of federal law and binding minimal standards that govern the practice of pharmacy in the State of Florida.

ONGOING CONDUCT

14. As noted, Respondent has repeatedly filled controlled substance prescriptions in the face of obvious, unresolved red flags of abuse and/or diversion. Respondent has continued to fill such prescriptions through at least October 21, 2022, without addressing and resolving these red flags.

IN view of the foregoing, and based on the information before the Agency as of the issuance of this notice, it is the Agency's preliminary finding, pursuant to 21 U.S.C. §§ 823(g)(1) and 824(a)(4), that the Pharmacy's continued registration is inconsistent with the public interest. It is the Agency's preliminary finding that the Pharmacy repeatedly dispensed controlled substances without properly attempting to address or resolve clear red flags of drug abuse or diversion, which is inconsistent with the public interest. It is also the Agency's preliminary finding that the Pharmacy's continued registration during the pendency of these proceedings would constitute "an imminent danger to the public health or safety" because of the "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur" in the absence of this suspension. 21 U.S.C. § 824(d). Under the facts and circumstances described herein, it is the Agency's conclusion that the Pharmacy's continued registration while these proceedings are pending constitutes "an imminent danger to the public health or safety." *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted the Agency's under 28 C.F.R. § 0.100, DEA COR No. FS0588004 is hereby suspended effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that the Pharmacy possesses pursuant to the registration that the Agency has herein suspended. The said Agents and Investigators are also directed to take into their possession Respondent's DEA COR No. FS0588004, and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Respondent fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Should Respondent request a hearing and fail to timely file an answer, plead, or otherwise defend, or should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and to be in default, and DEA may enter an order terminating the proceeding. *See* 21 C.F.R. §§ 1301.43(c)(2), (c)(3), (d).

3. Default constitutes a waiver of Respondent's right to hearing and an admission of the factual allegations of this Order to Show Cause and Immediate Suspension of Registration. *See* 21 C.F.R. § 1301.43(e). In the event that Respondent is deemed in default or an order terminating the proceedings has been issued, DEA may enter a default final order pursuant to 21 C.F.R. § 1316.67. *See* 21 C.F.R. § 1301.43(f)(1).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@dea.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@dea.gov. Other correspondence concerning this matter, including the request referenced in paragraph 1, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served separately on Government counsel, Paula M. Trahos and David M. Locher, and be addressed to the Office of Chief Counsel, Diversion Section, 8701 Morrissette Drive, Springfield, VA 22152.

Anne Milgram
Administrator

cc: Hearing Clerk, Office of Administrative Law Judges
Paula M. Trahos and David M. Locher, Counsel for the Government