U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, Va 22152*

January 3, 2020

IN THE MATTER OF

AARRIC, Inc.
d/b/a/ AT COST RX
16970 San Carlos Boulevard, Suite 110
Fort Myers, Florida 33908

DEA Certificate of Registration No. FA2125640

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 AARRIC, Inc. ("AARRIC" or "Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration ("COR") No. FA2125640, 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 Respondent an opportunity to show cause before the DEA in Arlington, VA, or at a location designated by the Administrative Law Judge, on March 3, 2020, (if Respondent requests such a hearing), as to why the 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 the 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(f).

As detailed below, this order states the 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 AARRIC has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which the DEA construes *in pari materia*). In order for AARRIC to preserve its rights in this proceeding, AARRIC may appear in these revocation proceedings by filing a notice of appearance or request for hearing in the manner prescribed by regulations within 30 days from the receipt of this Order.

1. AARRIC is registered with the DEA to handle controlled substances in Schedules II–V under DEA COR No. FA2125640. AARRIC's registered address is 16970 San Carlos Boulevard, Suite 110, Fort Myers, Florida 33908. AARRIC's COR expires by its own terms on June 30, 2022.

2. AARRIC's DEA COR should be revoked and any pending application should be denied because AARRIC has committed such acts as would render its registration inconsistent with the public interest under 21 U.S.C. § 823(f). *See* 21 U.S.C. § 824(a)(4). From February 19, 2018, until at least September 16, 2019, AARRIC repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that the prescriptions were issued for a legitimate medical purpose, in violation of federal and state law. Given AARRIC's longstanding and pervasive violations of legal requirements relating to the practice of pharmacy, AARRIC's continued registration constitutes an imminent danger as defined by 21 U.S.C. § 824(d).

LEGAL REQUIREMENTS

3. 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. Pharmacists at AARRIC were 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. 7,304, 7,331 (2018).

4. In addition to complying with federal statutes and regulations, AARRIC 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," "drug–drug interactions," 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." *Id.* at r. 64B16-27.810(2). Florida pharmacists must also maintain a patient record system that documents resolution of red flags. *See id.* at r. 64B16-27.800. Finally, Florida pharmacists must comply with the standards for filling of controlled substance prescriptions. *See id.* at 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. 7,304, 7,329 (2018) ("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 C.F.R. § 1306.04(a).").

5. As explained in greater detail below, a Florida pharmacy expert retained by the DEA has reviewed numerous prescriptions filled by AARRIC, AARRIC's corresponding patient profiles, and the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program ("E-FORSCE")[1] report of prescriptions filled by AARRIC, and has concluded that from February 19, 2018, until at least September 16, 2019, AARRIC repeatedly filled prescriptions for controlled substances in violation of binding minimal standards that govern the practice of pharmacy in the State of Florida.

COCKTAIL MEDICATIONS

6. As discussed above, both federal and Florida law require pharmacists to identify and resolve red flags of abuse and diversion. *See* paragraph 4, *supra*. One common red flag of drug abuse or diversion is when a practitioner prescribes "cocktail medications." Cocktail medications are combinations of controlled substances that are widely known to be abused or diverted, and when taken together create or enhance abusive or euphoric effects, but also significantly increase a patient's risk of death or overdose. The DEA's expert concluded that AARRIC regularly dispensed such cocktail medications without addressing or resolving this red flag. For example, the DEA's expert noted that AARRIC repeatedly dispensed high doses of opioids (in the form of hydromorphone, oxycodone, methadone, or morphine sulfate extended release) along with high doses of other central nervous system depressant medications, such as benzodiazepines (e.g., alprazolam or temazepam). The DEA's expert opined that not only are these controlled substances dangerous when used in combination, but that in 2016, the Centers for Disease Control and Prevention ("CDC") released guidelines highlighting the increased risk that combining opioids and benzodiazepines poses to patients.

7. AARRIC repeatedly dispensed cocktail medications without any indication that its pharmacists addressed or resolved the fact that such prescriptions present a risk of abuse or diversion. Examples of instances when AARRIC dispensed cocktail medications in the face of unresolved red flags include the following:

   a. On at least 18 occasions between April 10, 2018, and September 11, 2019, AARRIC filled prescriptions written on the same day by Physician A.N. for Patient D.H. for 120 units of hydromorphone 8 mg (a Schedule II opioid), 60 units of morphine sulfate extended release 30 mg (a Schedule II opioid), and 60 units of alprazolam 2 mg (a Schedule IV benzodiazepine).

[1] E-FORSCE is Florida's prescription drug monitoring program.

b. On at least eight occasions between August 29, 2018, and May 2, 2019, AARRIC filled prescriptions written on the same day by Physician M.L. for Patient J.W. for 112 units of oxycodone 30 mg (a Schedule II opioid), 28 units of methadone 10 mg (a Schedule II opioid), and 30 units of alprazolam 1 mg (a Schedule IV benzodiazepine).

c. On at least 14 occasions between September 18, 2018, and September 16, 2019, AARRIC filled prescriptions written on the same day by Physician M.L. for Patient E.A. for 120 units of oxycodone 30 mg (a Schedule II opioid), 28 units of morphine sulfate extended release 30 mg (a Schedule II opioid), and 30 units of alprazolam 1 mg (a Schedule IV benzodiazepine).

d. On at least 13 occasions between October 4, 2018, and September 4, 2019, AARRIC filled prescriptions written on the same day by Physician M.L. for Patient S.D. for 120 units of oxycodone 30 mg (a Schedule II opioid), 21–30 units of morphine sulfate extended release 30 mg (a Schedule II opioid), and 30 units of alprazolam 1 mg (a Schedule IV benzodiazepine).

e. On at least seven occasions between January 9, 2019, and August 23, 2019, AARRIC filled prescriptions written on the same day by Physician A.N. for Patient J.M. for 120 units of hydromorphone 8 mg (a Schedule II opioid), 60 units of morphine sulfate extended release 30 mg (a Schedule II opioid), 60 units of alprazolam 2 mg (a Schedule IV benzodiazepine), and 30 units of temazepam 30 mg (a Schedule IV benzodiazepine).[2]

f. On at least seven occasions between January 11, 2019, and July 5, 2019, AARRIC filled prescriptions written on the same day by Physician A.N. for Patient D.K. for 120 units of hydromorphone 8 mg (a Schedule II opioid), 60 units of morphine sulfate extended release 60 mg (a Schedule II opioid), and 60 units of alprazolam 1 mg (a Schedule IV benzodiazepine).

g. On at least six occasions between February 19, 2019, and August 28, 2019, AARRIC filled prescriptions written on the same day by Physician M.L. for Patient C.W. for 120 units of hydromorphone 8 mg (a Schedule II opioid) and 30 units of alprazolam 1 mg (a Schedule IV benzodiazepine).

LONG DISTANCES

8. Between February 19, 2018, and September 16, 2019, AARRIC regularly filled controlled substance prescriptions for individuals who traveled an unusual distance to obtain their prescriptions. The DEA's expert opined that traveling long distances to obtain or fill a controlled substance is indicative of diversion and/or abuse, and that such behavior is a red flag that must be addressed prior to dispensing. *See* 21 C.F.R.

[2] On two of these occasions—March 7, 2019, and April 3, 2019—the prescription for temazepam was written and filled as 60 units of temazepam 15 mg, with the instruction to take a dose of two units. This prescription was equivalent to the other prescriptions for temazepam that Physician A.N. issued to Patient J.M. and AARRIC filled—30 units of temazepam 30 mg, with the instruction to take a dose of one unit.

§ 1306.04(a); 21 C.F.R. § 1306.06; and Fla. Admin. Code Ann. r. 64B16-27.810. AARRIC did not do so, as illustrated by the following examples of prescriptions that it filled:

a. On at least 16 occasions between February 19, 2018, and April 15, 2019, Patient J.A. traveled over 53 miles round trip to AARRIC to obtain prescriptions for 112–120 units of hydromorphone 8 mg. Patient J.A. again traveled the same distance to AARRIC to obtain prescriptions for 90 units of hydromorphone 8 mg on July 8, 2019, and August 5, 2019.

b. On at least 17 occasions between March 6, 2018, and September 11, 2019, Patient L.H. traveled over 78 miles round trip to AARRIC to obtain prescriptions for 120–140 units of oxycodone 30 mg and 28–60 units of morphine sulfate extended release 30 mg.

c. On at least 20 occasions between March 7, 2018, and August 21, 2019, Patient S.T. traveled 66 miles round trip to AARRIC to obtain prescriptions for 150 units of oxycodone 30 mg and 60 units of morphine sulfate extended release 60 mg.

d. On at least eight occasions between August 29, 2018, and May 2, 2019, Patient J.W. traveled over 71 miles round trip to AARRIC to obtain prescriptions for 112 units of oxycodone 30 mg, 28 units of methadone 10 mg, and 30 units of alprazolam 1 mg.

e. On at least 14 occasions between September 19, 2018, and September 16, 2019, Patient E.A. traveled over 45 miles round trip to AARRIC to obtain prescriptions for 120 units of hydromorphone 8 mg, 28 units of morphine sulfate extended release 30 mg, and 30 units of alprazolam 1 mg.

f. On at least six occasions between January 11, 2019, and June 6, 2019, Patient D.K. traveled 44 miles round trip to AARRIC to obtain prescriptions for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 60 mg, and 60 units of alprazolam 1 mg. Patient D.K. subsequently traveled over 42 miles round trip to AARRIC to obtain the same prescriptions on July 5, 2019, and to obtain prescriptions for 90 units of hydromorphone 8 mg and 90 units of alprazolam 0.5 mg on August 30, 2019.

IMPROPER DOSING FOR PAIN MANAGEMENT

9. As noted above, both federal and Florida law require a pharmacist to identify and address red flags of drug abuse or diversion including over-utilization, under-utilization, and therapeutic duplication. *See* 21 C.F.R. §§ 1306.04(a), 1306.06; Fla. Admin. Code Ann. r. 64B16-27.810. According to the DEA's expert, for a patient receiving treatment with both long-acting and short-acting opioids, the proper pharmacologic dosing for pain management is to use larger, scheduled doses of the long-acting opioid to control chronic pain with smaller, as-needed doses of the short-acting opioid for breakthrough pain. According to the DEA's expert, this method of dosing reduces the amount of the short-acting opioid that the patient must use in order to obtain the same level of pain control. In contrast, the DEA's expert opined that prescriptions that provide a larger daily dose of

short-acting opioids, rather than long-acting opioids, do not make pharmacologic sense and thus are a red flag of drug abuse or diversion.

10. From at least March 5, 2018, through at least September 16, 2019, AARRIC repeatedly filled prescriptions for patients receiving a much greater daily morphine milligram equivalent dosage of short-acting opioids than long-acting opioids. The DEA's expert also noted that each of the short-acting or immediate release opioid prescriptions was scheduled four times a day (for Patients E.A., S.D., L.H., and J.M.) or five times a day (for Patient S.T.) even though the patients were also prescribed a scheduled, long-acting opioid. The DEA's expert reviewed AARRIC's patient profiles for these patients and the E-FORSCE report of the controlled substances that AARRIC dispensed. In the expert's view, because these prescriptions were illogical from a pharmacological perspective, they therefore raised a red flag. The DEA's expert further opined that AARRIC should have attempted to address or resolve this red flag of drug abuse or diversion prior to filling these prescriptions, but, on numerous occasions, AARRIC and its pharmacists failed to do so. Examples of AARRIC filling such improper prescriptions include the following:

    a. On at least 19 occasions between March 5, 2018, and August 23, 2019, AARRIC filled prescriptions for Patient J.M. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

    b. On at least 20 occasions between March 7, 2018, and August 21, 2019, AARRIC filled prescriptions for Patient S.T. for 150 units of immediate release oxycodone 30 mg (equal to 225 mg of morphine per day), but only 60 units of morphine sulfate extended release 60 mg (equal to 120 mg of morphine per day).

    c. On at least 18 occasions between April 10, 2018, and September 11, 2019, AARRIC filled prescriptions for Patient D.H. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

    d. On at least 15 occasions between August 9, 2018, and September 4, 2019, AARRIC filled prescriptions for Patient S.D. for 120 units of immediate release oxycodone 30 mg (equal to 180 mg of morphine per day), but only 30 units of morphine sulfate extended release 30 mg (equal to 30 mg of morphine per day).

    e. On at least 14 occasions between August 28, 2018, and September 11, 2019, AARRIC filled prescriptions for Patient L.H. for 120 units of immediate release oxycodone 30 mg (equal to 180 mg of morphine per day), but only 28 units of morphine sulfate extended release 30 mg (equal to 30 mg of morphine per day).[3]

[3] Each of Patient L.H.'s prescriptions provided him with only a 28-day supply of morphine sulfate extended release 30 mg, notwithstanding the fact that they provided him with a 30-day supply of oxycodone 30 mg. Nevertheless, AARRIC filled the prescriptions.

f. On at least 14 occasions between September 19, 2018, and September 16, 2019, AARRIC filled prescriptions for Patient E.A. for 120 units of immediate release oxycodone 30 mg (equal to 180 mg of morphine per day), but only 28 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day for 14 days, as the dosage was two units per day).[4]

IMPROPER DOSING OF BENZODIAZEPINES

11. The DEA's expert also noted that Physician M.L.'s prescriptions for alprazolam to Patients J.W., E.A., and S.D., described in paragraphs 7(b)–(d), *supra*, were each written as prescriptions for 30 units of alprazolam 1 mg, even though Physician M.L.'s instruction for dosing was to take only half a tablet—that is, 0.5 mg—every 12 hours. AARRIC dispensed each of these prescriptions to Patients J.W., E.A., and S.D., as 30 units of alprazolam 1 mg. The DEA's expert opined that, given the commercial availability of alprazolam in 0.5 mg doses at minimal expense, there was no pharmacological reason for Physician M.L. to write or for AARRIC to dispense prescriptions for alprazolam using 1 mg units where the instructed dosage was only 0.5 mg. In the expert's view, because these prescriptions were illogical from a pharmacological perspective, they therefore raised a red flag. The DEA's expert further opined that the likely reason for the use of 1 mg units instead of 0.5 mg units was to increase the illicit value of these prescriptions for purposes of diversion. The DEA's expert concluded that AARRIC should have attempted to address or resolve this red flag of drug abuse or diversion before filling these prescriptions, but, on numerous occasions, AARRIC and its pharmacists failed to do so.

12. The DEA's expert further noted that, as described in paragraph 7(e), *supra*, on at least seven occasions between January 9, 2019, and August 23, 2019, AARRIC filled prescriptions for Patient J.M. for both 60 units of alprazolam 2 mg and 30 units of temazepam 30 mg. The DEA's expert opined that prescribing multiple benzodiazepines to a single patient constitutes therapeutic duplication. The DEA's expert explained that such therapeutic duplication is highly dangerous, especially if the patient is also prescribed opioids, because benzodiazepines and opioids are respiratory depressants. The DEA's expert concluded that AARRIC should have attempted to address or resolve this red flag of drug abuse or diversion before filling these prescriptions, but, on numerous occasions, AARRIC and its pharmacists failed to do so.

CASH PAYMENTS

13. Another common red flag of abuse or diversion that pharmacists must monitor, is the use of cash payments for controlled substances instead of insurance payments. *See* 21 C.F.R. §§ 1306.04(a), 1306.06; Fla. Admin. Code Ann. r. 64B16-27.810. According to the DEA's expert, when a prescription for a controlled substance is electronically processed through insurance, the insurance company will frequently reject suspicious controlled substance prescriptions that may be related to drug abuse or diversion, such as controlled

[4] Each of Patient E.A.'s prescriptions provided him with only a 14-day supply of morphine sulfate extended release 30 mg, notwithstanding the fact that they provided him with a 30-day supply of oxycodone 30 mg. Nevertheless, AARRIC filled the prescriptions.

prescriptions for the same patient filled at multiple pharmacies. Consequently, cash payments for controlled substance prescriptions are a red flag of abuse or diversion because some suspect patients may choose to pay cash in order to avoid an insurance rejection that might alert the pharmacist to potential drug abuse or 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 or 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)). Such cash payments are especially suspicious when the patient bills insurance for other prescriptions, but pays cash for controlled substance prescriptions. The DEA's expert noted that each of the prescriptions described in paragraphs 6 through 12, *supra*, was paid for with cash. The DEA's expert concluded that AARRIC should have attempted to address or resolve this red flag of drug abuse or diversion before filling these prescriptions, but, on numerous occasions, AARRIC and its pharmacists failed to do so.

IN view of the foregoing, and based on the information before the Agency as of the issuance of this notice, it is my preliminary finding, pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), that AARRIC's continued registration is inconsistent with the public interest. It is my preliminary finding that AARRIC repeatedly dispensed controlled substances without attempting to address or resolve clear red flags of drug abuse or diversion, which is inconsistent with the public interest. It is also my preliminary finding that AARRIC'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 my conclusion that AARRIC'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 me under 28 C.F.R. § 0.100, DEA COR No. FA2125640 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 the 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 AARRIC possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession AARRIC's DEA COR No. FA2125640 and any unused order forms.

THE following procedures are available to AARRIC in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, AARRIC may file with the 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 AARRIC fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, AARRIC may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should AARRIC decline to file a request for a hearing, or should AARRIC request a hearing and then fail to appear at the designated hearing, AARRIC shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@usdoj.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@usdoj.gov. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. A copy of the same shall also be served separately on Government counsel, Paul Dean and Joshua Packman, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.

Uttam Dhillon
Acting Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Paul A. Dean, Counsel for the Government
Joshua H. Packman, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

(A) [State with particularity the interest of the person in the proceeding.]

(B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]

(C) [State briefly the position of the person with regard to the particular objections or issues.]

(D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.