



Office of the Administrator

Springfield, VA 22152

November 18, 2019

IN THE MATTER OF

Gulf Med Pharmacy, Inc.
Certificate of Registration No. FG6290061
4106 Del Prado Boulevard South
Cape Coral, Florida 33904

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 Gulf Med Pharmacy, Inc. ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration ("COR") No. FG6290061, 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, Virginia, or at a location designated by the Administrative Law Judge, on January 7, 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 Gulf Med Pharmacy has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which the DEA construes *in pari materia*). In order for Gulf Med Pharmacy to preserve its rights in this proceeding, Gulf Med Pharmacy must 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.

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1. Gulf Med Pharmacy is registered with the DEA to handle controlled substances in Schedules II-V under DEA COR No. FG6290061. Gulf Med Pharmacy's registered address is 4106 Del Prado Boulevard South, Cape Coral, Florida 33904. Gulf Med Pharmacy's COR expires by its own terms on September 30, 2022.
2. Gulf Med Pharmacy's DEA COR should be revoked and any pending application should be denied because Gulf Med Pharmacy 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 March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that they were issued for a legitimate medical purpose, in violation of federal and state law. Given Gulf Med Pharmacy's longstanding and pervasive violations of legal requirements relating to the practice of pharmacy, Gulf Med Pharmacy's continued registration constitutes an "imminent danger" as that term is 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 Gulf Med Pharmacy 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, alteration in original).
4. In addition to complying with federal statutes and regulations, Gulf Med 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," "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 pharmacies 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 Gulf Med Pharmacy and has concluded that from March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy 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 (via one or more prescriptions) “cocktail medications.” Cocktail medications are combinations of controlled substances that are widely known to be abused or diverted, and when taken together, significantly increase a patient’s risk of death or overdose. The DEA’s expert reviewed numerous prescriptions filled by Gulf Med Pharmacy, as well as Gulf Med Pharmacy’s patient profiles for the relevant patients, and concluded that Gulf Med Pharmacy regularly dispensed cocktail medications without addressing or resolving this red flag. For example, the DEA’s expert noted that Gulf Med Pharmacy repeatedly dispensed high doses of opioids (in the form of hydromorphone, oxycodone, and morphine sulfate extended release) along with high doses of other central nervous system depressant medications, such as benzodiazepines (*e.g.*, alprazolam, clonazepam, or diazepam) or muscle relaxants (*e.g.*, carisoprodol). The DEA’s expert opined that these controlled substances are dangerous when used in combination.
7. Gulf Med Pharmacy 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 Gulf Med Pharmacy dispensed cocktail medications in the face of unresolved red flags include the following:
 - a. On at least three occasions between May 22, 2019, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician R.D. for Patient A.B. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 15 mg, and 30 units of diazepam 10 mg.
 - b. On at least four occasions between February 9, 2018, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient B.Di. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 30 mg, and 60–90 units of alprazolam 1 mg.

- c. On at least five occasions between December 28, 2018, and August 8, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient J.B. for 120 units of oxycodone 30 mg, 60 units of morphine sulfate extended release 30 mg, and 90 units of alprazolam 1 mg.
 - d. On at least four occasions between May 14, 2019, and August 6, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician M.L. for Patient R.R. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 60 mg, and 30 units of alprazolam 2 mg.
 - e. On at least four occasions between May 8, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician M.L. for Patient B.Da. for 120 units of hydromorphone 8 mg, 30 units of morphine sulfate extended release 30 mg, and 30 units of alprazolam 2 mg. On February 12, 2018, Gulf Med Pharmacy also filled prescriptions written on the same day by another physician in the same practice—Physician D.P.—for Patient B.Da. for 150 units of hydromorphone 8 mg, 90 units of methadone 10 mg, and 30 units of alprazolam 2 mg.
8. According to the DEA's expert, the cocktail of an opioid, a benzodiazepine, and carisoprodol—commonly known as the "Trinity" cocktail—is a particularly serious red flag because that combination of controlled substances is highly dangerous and is widely known to be abused and/or diverted. Gulf Med Pharmacy repeatedly dispensed Trinity 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 Gulf Med Pharmacy dispensed Trinity cocktail medications in the face of unresolved red flags include the following: Between May 30, 2019, and July 29, 2019, Gulf Med Pharmacy filled three sets of prescriptions from Physicians D.G. and F.M. for Patient J.R. for the Trinity cocktail. For each set of prescriptions, Physician F.M. prescribed Patient J.R. benzodiazepines and muscle relaxants; specifically, 30 units of temazepam 30 mg, 30–60 units of diazepam 5 mg, and 120 units of carisoprodol 350 mg. Meanwhile, Physician D.G. prescribed Patient J.R. opioids; specifically, 120 units of Norco (hydrocodone–acetaminophen) 5–325 mg, 120 units of Percocet (oxycodone–acetaminophen) 5–325 mg, and 120 units of Percocet 10–325 mg.

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 and under-utilization. See 21 C.F.R. § 1306.04(a); 21 C.F.R. § 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 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy 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 or every six hours, even though the patient was also prescribed a scheduled, long-acting opioid. The DEA's expert reviewed Gulf Med Pharmacy's patient profiles for several of these patients. 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 Gulf Med Pharmacy should have attempted to address or resolve this red flag of drug abuse or diversion prior to filling these prescriptions, but, on numerous occasions, its pharmacists failed to do so. Examples of Gulf Med Pharmacy filling such improper prescriptions include the following:
 - a. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient A.B. 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 15 mg (equal to 30 mg of morphine per day).
 - b. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient B.Di. 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).
 - c. On at least 18 occasions between January 10, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for Patient S.K. for 110 units of immediate release hydromorphone 8 mg (equal to 125–128 mg of morphine per day), but only 60 units of morphine sulfate extended release 15 mg (equal to 30 mg of morphine per day).
 - d. On at least 27 occasions between March 22, 2017, and August 8, 2019, Gulf Med Pharmacy filled prescriptions for Patient J.B. for 108–120 units of immediate release oxycodone 30 mg (equal to 162–180 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).
 - e. On at least eight occasions between October 2, 2018, and August 6, 2019, Gulf Med Pharmacy filled prescriptions for Patient R.R. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 28 units of morphine sulfate extended release 60 mg (equal to 60 mg of morphine per day).
 - f. On at least eight occasions between January 16, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for Patient B.Da. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 30 units of morphine sulfate extended release 30 mg (equal to 30 mg of morphine per day).

LONG DISTANCES

11. Between October 25, 2017, and August 5, 2019, Gulf Med Pharmacy 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. § 1306.04(a); 21 C.F.R. § 1306.06; Fla. Admin. Code. Ann. r. 64B16-27.810. Gulf Med Pharmacy did not do so, as illustrated by the following examples of prescriptions that it filled:
 - a. On at least 20 occasions between November 8, 2017, and July 17, 2017, Patient A.B. traveled 45 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 15 mg, and diazepam 10 mg, which Gulf Med Pharmacy filled.
 - b. On at least five occasions between October 25, 2017, and February 12, 2018, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg and methadone 10 mg, which Gulf Med Pharmacy filled. On two of those trips—January 15, 2018, and February 12, 2018—Patient B.Da. also obtained prescriptions for alprazolam 2 mg, which Gulf Med Pharmacy also filled. Subsequently, on at least seven occasions between February 13, 2019, and August 5, 2019, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 30 mg, and alprazolam 2 mg, which Gulf Med Pharmacy also filled.
 - c. On at least 17 occasions between January 17, 2018, and May 8, 2019, Patient R.D. traveled over 41 miles round trip to obtain prescriptions for hydromorphone 8 mg and lorazepam 2 mg, which Gulf Med Pharmacy filled.

CASH PAYMENTS AND PRICE GOUGING/BLACK MARKET PRICING

12. 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); 21 C.F.R. § 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 substance prescriptions for the same patient filled at multiple pharmacies. Consequently, cash payments for controlled 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. Such cash payments are especially suspicious when the patient bills insurance for other prescriptions, but pays cash for controlled substance prescriptions.

13. Similarly, the DEA's expert indicated that price gouging, or charging more than the market rate for prescriptions for a controlled substance, is a separate indicator of drug abuse or diversion. The DEA's expert explained that price gouging is a red flag because a legitimate patient, who could fill his or her prescription at any pharmacy, will switch pharmacies in order to pay the fair market price for that prescription. In contrast, the highly suspect patient can only fill prescriptions at a suspicious pharmacy and must pay whatever price that suspicious pharmacy sets. Consequently, patients paying inflated prices for controlled substance prescriptions are another red flag of drug abuse or diversion, especially when the price paid is substantially higher than the market price available from other nearby pharmacies. See *Jones Total Health Care Pharmacy, L.L.C.*, 81 Fed. Reg. 79,188, 79,191 (2016). For the same reason, filling controlled substance prescriptions at inflated cash prices shows that a pharmacy has knowledge that it is filling prescriptions that are not legitimate, as its inflated prices reflect a "risk premium" that the pharmacy charges to account for the risk it is taking by filling illegitimate prescriptions. See *id.* at 79,199-200 ("[E]ven granting that there are no prohibitions on the prices a pharmacy can charge for controlled substances, when those prices far exceed what other pharmacies would charge, the Agency may properly draw the inference that the pharmacy is charging those prices because it knows it is supplying persons who are seeking the drugs to either abuse them or divert them to others."). To determine a baseline of normalcy (*i.e.*, legitimate pricing), the DEA's expert contacted representative pharmacies in Cape Coral, Florida, and found that the price of 120–140 units of oxycodone 30 mg varied from about \$1.59 to \$1.63 per unit, while the sale price of 120–140 units of hydromorphone 8 mg varied from about \$1.25 to \$1.27 per unit.
14. From March 22, 2017, until at least August 6, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for oxycodone 30 mg and hydromorphone 8 mg for patients who paid for these prescriptions in cash at substantially inflated prices that far exceeded what other area pharmacies charged. The DEA's expert reviewed Gulf Med Pharmacy's patient profiles for several of these patients. The DEA's expert opined that Gulf Med Pharmacy should have attempted to address or resolve these red flags of drug abuse or diversion prior to filling these prescriptions, but failed to do so. Gulf Med Pharmacy dispensed controlled substances at inflated prices to individuals paying cash in the following instances:
- On at least 15 separate occasions between March 14, 2018, and April 10, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient R.D. On each occasion, Patient R.D. paid for the prescription in cash, and on all but one occasion Patient R.D. paid \$4 per unit (\$480 in total)—over three times the market rate.
 - On at least six separate occasions between February 26, 2018, and April 22, 2019, Gulf Med Pharmacy filled prescriptions for 84 to 120 units of oxycodone 30 mg for Patient T.G. On each occasion, Patient T.G. paid for the prescription in cash at a price of \$4 per unit (\$336 to \$480 in total)—over three times the market rate.

- c. On at least 16 separate occasions between March 7, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for 108 to 110 units of hydromorphone 8 mg for Patient S.K. On each occasion, Patient S.K. paid for the prescription in cash at a price ranging from \$3.56 per unit to \$4 per unit (\$392 to \$432 in total)—in each case at least two-and-a-half times the market rate, and as high as over three times the market rate.
- d. On at least 14 separate occasions between March 20, 2018, and April 15, 2019, Gulf Med Pharmacy filled prescriptions for 90 to 120 units of oxycodone 30 mg for Patient L.V. On each occasion, Patient L.V. paid for the prescription in cash at a price ranging from \$2.50 per unit to \$3.33 per unit (\$300 in total)—in each case at least one-and-a-half times the market rate, and as high as twice the market rate. Further, Patient L.V. used insurance to pay for other prescriptions, including prescriptions for controlled substances such as alprazolam and zolpidem.
- e. On at least 19 separate occasions between March 22, 2017, and September 7, 2018, Gulf Med Pharmacy filled prescriptions for 108 to 120 units of oxycodone 30 mg for Patient J.B. On each occasion, Patient J.B. paid for the prescription in cash at a price of \$3.40 to \$4 per unit (\$408 to \$480 in total)—in each case over twice the market rate.
- f. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient A.B. On each occasion, Patient A.B. paid for the prescription in cash at a price of \$3.73 to \$4 per unit (\$448 to \$480 in total)—in each case over two-and-a-half times the market rate, and as high as three times the market rate.
- g. On at least five occasions between October 25, 2017, and February 12, 2018, Gulf Med Pharmacy filled prescriptions for 150 units of hydromorphone 8 mg for Patient B.Da. Subsequently, on at least six occasions between March 13, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Da. On each of these 11 occasions, Patient B.Da. paid for the prescription in cash at a price of \$4 per unit (\$480 to \$600 in total)—over three times the market rate.
- h. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Di. On each occasion, Patient B.Di. paid for the prescription in cash at a price of \$4 per unit (\$480 in total)—over three times the market rate.
- i. On at least 18 occasions between December 5, 2017, and least August 6, 2019, Gulf Med Pharmacy filled prescriptions for 120 to 168 units of hydromorphone 8 mg for Patient R.R. On each occasion, Patient R.R. paid for the prescription in cash at a price ranging from \$4 per unit to \$4.60 per unit (\$480 to \$672 in total)—in each case over three times the market rate.

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 Gulf Med Pharmacy's continued registration is inconsistent with the public interest. It is my preliminary finding that Gulf Med Pharmacy 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 Gulf Med 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 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 Gulf Med 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 me under 28 C.F.R. § 0.100, DEA COR No. FG6290061 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 Gulf Med Pharmacy possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Gulf Med Pharmacy's DEA COR No. FG6290061 and any unused order forms.

THE following procedures are available to Gulf Med Pharmacy in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Gulf Med Pharmacy 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 Respondent 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, Respondent 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 Gulf Med Pharmacy decline to file a request for a hearing, 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 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 Morrisette Drive, Springfield, VA 22152. A copy of the same shall also be served separately on Government counsel, Joshua Packman, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.



Uttam Dhillon
Acting Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
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 Morrisette 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.

U. S. Department of Justice - Drug Enforcement Administration	DEA USE ONLY
SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION	File No. _____

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list I chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

NAME OF REGISTRANT (<i>Print</i>)	ADDRESS OF REGISTRANT
DEA REGISTRATION NO.	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL	DATE

WITNESSES TO REGISTRANT'S SIGNATURE	
NAME AND DATE	TITLE
NAME AND DATE	TITLE

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C. 821).
PURPOSE: Permit surrender for cause of DEA Certificate of Registration.
ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided.