



## FLORIDA DEPARTMENT *of* STATE

**RON DESANTIS**  
Governor

**CORD BYRD**  
Secretary of State

September 20, 2023

Angela M. Southwell  
Paralegal Specialist  
Office of the Attorney General  
PL-01 The Capitol  
Tallahassee, Florida 32399-1050

Dear Angela M. Southwell:

Your adoption package for Emergency Rule 2ER23-1 was received, electronically, by the Florida Department of State, Administrative Code and Register at 3:59 p.m. on September 20, 2023. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is September 20, 2023.

Sincerely,

Anya C. Owens  
Administrative Code and Register Director

ACO/al

## Leijon, Alexandra

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**From:** Angela Southwell <Angela.Southwell@myfloridalegal.com>  
**Sent:** Wednesday, September 20, 2023 3:59 PM  
**To:** RuleAdoptions  
**Cc:** Owens, Anya C.; Leijon, Alexandra  
**Subject:** Adoption Packet for Department of Legal Affairs Emergency Rule 2ER23-1  
**Attachments:** Adoption Pkt 2ER23-1.pdf; ADOPTION TEXT EMERGENCY RULE 2ER23-1.docx

EMAIL RECEIVED FROM EXTERNAL SOURCE

The attachments/links in this message have been scanned by Proofpoint.

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Good Afternoon:

Attached please find the adoption packet and text for the above referenced rule.

Angela M. Southwell  
Paralegal Specialist  
Office of the Attorney General  
Administrative Law  
PL-01 The Capitol  
Bin #4100  
Tallahassee, Florida 32399-1050  
Telephone: (850) 414-3772  
[angela.southwell@myfloridalegal.com](mailto:angela.southwell@myfloridalegal.com)



**ASHLEY MOODY**  
**ATTORNEY GENERAL**  
**STATE OF FLORIDA**

**OFFICE OF THE ATTORNEY GENERAL**  
**Administrative Law**

Angela Southwell  
Paralegal Specialist  
PL-01 The Capitol  
Tallahassee, FL 32399-1050  
Phone (850) 414-3772  
Fax (850) 922-6425  
[angela.southwell@myfloridalegal.com](mailto:angela.southwell@myfloridalegal.com)

## **MEMORANDUM**

**TO:** Anya Owens, Program Administrator  
Administrative Code and Register

**FROM:** Angela Southwell, Paralegal Specialist

**RE:** Department of Legal Affairs Emergency Rule 2ER23-1

**DATE:** September 20, 2023

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Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Findings of the Attorney General In Support of Emergency Rule 2ER23-1
- Notice of Emergency Rule
- Adoption text for Emergency Rule 2ER23-1 (double spaced)
- Certification of the Department of Legal Affairs Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification

Should you have any questions regarding the rule, please contact me at [angela.southwell@myfloridalegal.com](mailto:angela.southwell@myfloridalegal.com) or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF THE  
DEPARTMENT OF LEGAL AFFAIRS EMERGENCY RULE  
FILED WITH THE DEPARTMENT OF STATE


I hereby certify that an immediate danger to the public health, safety or welfare requires emergency action and that the attached rule is necessitated by the immediate danger. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with section 120.54(4), F.S. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No.

2ER23-1

Under the provision of Section 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing, is set out below:

Effective Date: \_\_\_\_\_  
(Month) (Day) (Year)

  
\_\_\_\_\_  
Ashley Moody  
Attorney General

\_\_\_\_\_  
Attorney General  
Title

\_\_\_\_\_  
Number of Pages Certified

**DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION  
CERTIFICATION**

Pursuant to Section 120.695(2)(c)3, Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), Florida Statutes, that:

[xx] All rules covered by this certification are not rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.

[ ] The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No(s).

2ER23-1

A handwritten signature in dark ink, appearing to read "Ashley Moody", is written over a horizontal line.

Ashley Moody  
Attorney General

Attorney General  
Title

## NOTICE OF EMERGENCY RULE

DEPARTMENT OF LEGAL AFFAIRS

RULE NO.: RULE TITLE:

2ER23-1     Addition of TIANEPTINE (7-((3-chloro-6-methyl-5,5-dioxido-6,11-dihydrodibenzo[c,f][1,2]thiazepin-11-yl)amino)heptanoic acid  
TO SCHEDULE I, SUBSECTION 893.03(1)(a), F.S.

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC, HEALTH, SAFETY OR WELFARE:

In written findings published on the date this emergency rule was filed with the Secretary of State's Office, Attorney General Ashley Moody has found that there is a need to immediately place the above-mentioned substance under Schedule I, Subsection 893.03(1)(a), F.S., in order to curtail its abuse by Florida's children, young adults, and others. These circumstances present an immediate and imminent hazard to the public health, safety, and welfare which requires emergency action. In addition, the Attorney General has found that the above-mentioned compound meets the statutory criteria for placement as a controlled substance in Schedule I, subsection 893.03(1)(a), F.S.

REASONS FOR CONCLUDING THAT THE PROCEDURE USED IS FAIR UNDER THE CIRCUMSTANCES:

The above-mentioned compound presents an immediate and imminent hazard to the public health, safety, and welfare which requires emergency action. The Attorney General will ask the Florida Legislature to memorialize this action through legislation in its 2024 legislative session. A copy of the Attorney General's findings in support of this emergency rule may be obtained by contacting the Office of the Attorney General, PL-01 The Capitol, Tallahassee, Florida 32399-1050; (850) 245-0145.

SUMMARY: The proposed emergency rule adds TIANEPTINE (7-((3-chloro-6-methyl-5,5-dioxido-6,11-dihydrodibenzo[c,f][1,2]thiazepin-11-yl)amino)heptanoic acid to Schedule I, subsection 893.03(1)(a), F.S.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS:

Ashley Moody, Attorney General, PL-01 The Capitol, Tallahassee, Florida 32399-1050; (850) 245-0145.

STATE OF FLORIDA  
OFFICE OF THE ATTORNEY GENERAL

IN RE: EMERGENCY RULE,  
ADDING:

TIANEPTINE (7-((3-chloro-6-methyl-5,5-dioxido-6,11-dihydrodibenzo[c,f][1,2]thiazepin-11-yl)amino)heptanoic acid

TO SCHEDULE I, SUBSECTION 893.03(1)(a), F.S.

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FINDINGS OF THE ATTORNEY GENERAL  
IN SUPPORT OF EMERGENCY RULE 2ER23-1

Attorney General Ashley Moody finds there is currently an unregulated dietary substance being sold and abused in Florida and throughout the United States known as tianeptine containing the above-referenced chemical compound. The chemical structures of these compounds are dissimilar to any currently scheduled substance in Schedule I under Section 893.03, Florida Statutes.

Tianeptine, also known as “gas station heroin,” is an unscheduled synthesized pharmaceutical agent that is readily and widely available online, throughout Florida’s convenience stores and gas stations, and the illicit drug market. It is marketed as dietary or nootropic supplements, and commonly sold under the names of Coaxil, Pegasus, Red Dawn, Stablon, Tianaa, Tianna, and Za Za. The United States Food and Drug Administration (FDA) has labeled tianeptine as an unsafe food additive. It is easily obtained by minors and adults and has a high potential for abuse and death. Tianeptine has no currently accepted medical use in the United States and has been associated with 5 deaths across the country. Tianeptine is often found in combination with other illicit substances such as benzodiazepines and opioids.

Accordingly, Attorney General Moody finds that tianeptine presents an imminent hazard to the health, safety, and welfare of Floridians, and effective today, September 20, 2023, the Department of Legal Affairs adopts Emergency Rule 2ER23-1, which temporarily adds tianeptine to Schedule I, Subsection 893.03(1)(a), F.S.

ANALYSIS

When adopting an emergency rule controlling a substance under Chapter 893, Section 893.035(7)(a), Florida Statutes, requires the Attorney General to make a finding that the controlled substance is an imminent hazard to public safety and must consider the following factors:

- Whether the substance has potential for abuse
- Its history and current pattern of abuse
- The scope, duration, and significance of abuse
- Risk to public health

The consideration of the above-referenced factors shall include the actual abuse of the substance, its diversion from legitimate channels, and its clandestine importation, manufacture, and distribution.

A. Potential for Abuse

The Florida Department of Law Enforcement (FDLE), through the Florida Fusion Center, has identified tianeptine as a substance with high potential for abuse and no currently accepted medical use in treatment in the United States.<sup>1</sup> The U.S. Drug Enforcement Administration (DEA) has made similar findings in regards to

tianeptine in June 2023, as the availability and presence of the drug has increased on the web and in seizures.<sup>2</sup> Tianeptine is an atypical tricyclic antidepressant, which affects the mu- and delta-opioid and glutamate receptors (similarly to fentanyl and morphine), and can mimic the effects of opioid toxicity and withdrawal. As such, it has a high potential for abuse and can cause adverse health effects when consumed in larger doses or combined with other drugs including respiratory depression, mental confusion, loss of consciousness, and overdose-related death.

Several states surrounding Florida have already banned tianeptine and thus leaves Florida open for users to cross state lines to legally purchase tianeptine as reported by public forums. The highly addictive nature, severe withdrawal symptoms, and unregulated volume, potency, and purity of this “gas station heroin” can lead users to become dependent or back to opioids and other illicit drugs.

#### B. Scope, History, Duration, and Current Pattern of Abuse

Tianeptine is a tricyclic antidepressant that was developed in the 1960s in French pharmaceutical research laboratories in a search for an antidepressant. A prescription is required for the controlled substance in several European, Asian, and Latin American countries, in which it is used to primarily treat major depressive disorder. Current research has shown little, if any, serotonin inducing properties as the chemical makeup of tianeptine is unlike typical tricyclic antidepressants. Tianeptine has been available on the market since 2000 in powder or pill form.

During 2014-2017, tianeptine exposure calls in the U.S. increased tremendously compared to the previous 14 years when there were just 11 cases. In 2020 alone there were 151 cases. Mississippi’s Poison Control Center reported a substantial increase in calls from 0 in 2018 to about 17 calls in 2022. The greatest yield of data has come from the southern region of the United States and supports the current bans in states like Alabama, Georgia, and Mississippi. This trend is further supported by the U.S. Centers for Disease Control and Prevention’s (CDC) report that one-third of the 207 tianeptine exposure calls between 2014-2017 were from the southern census region.<sup>3</sup>

Tianeptine has appeared in Florida and at least 10 other states. Several countries have withdrawn tianeptine from the market since 2010 due to its potential for abuse. Also, a number of states have already listed tianeptine as a Schedule I or Schedule II controlled substance as early as 2018 and as recently as March 2023.

Florida’s Poison Control Center has had 15 exposure calls in the first half of 2023 alone, with users between the ages of 23 to 58. In 2022, 24 calls were reported, and 54 reported over the last 4 years. The reported users’ ages range from 18 to 66. Calls into the poison control center are voluntary, so the number of cases likely exceeds those reported. Nationally approximately 607 calls were made to poison control centers from 2020 to 2022.

Five deaths in the U.S. have been attributed to tianeptine intoxication. As recent as this year, Vermont confirmed one fatal overdose related to tianeptine, benzodiazepines, cocaine, and alcohol intoxication. The number of deaths attributed to tianeptine is suspected to be higher but cannot be confirmed.

It is believed that most tianeptine bought on the web is primarily shipped from China to the United States through common mail carriers. The average seizure weight of tianeptine is 1 kilogram (kg). However, in June 2023, the United States Custom and Border Protection agency seized a total of 43.37 kg arriving from China to the U.S. Tianeptine seizures have totaled over 350 kg in the last three fiscal years. For the most part, however, tianeptine is listed on the web with varying prices, and in gas stations with prices starting at \$30.00. In 2021, tianeptine sold for approximately \$7,000.00 per kg on the web. At this time there is no indication that large drug trafficking organizations are involved in the distribution of tianeptine but their increase in popularity may change these circumstances.

Tianeptine is often found in salt form, but has been encountered in bulk powder, and counterfeit pills mimicking hydrocodone and oxycodone pharmaceutical products. It has also appeared in individual stamp bags commonly used to distribute heroin.

C. Risk to Public Health

As previously noted, tianeptine is an antidepressant that chemically acts as mu-opioid receptor agonist that was developed for research purposes and the FDA has opined that it is not suitable for human use. Like opioid substances, tianeptine is known to produce side effects, some of which are quite severe. The side effects include:

- Respiratory Depression
- Loss of Consciousness
- Death
- Nausea
- Vomiting
- Agitation
- Decreased Blood Pressure
- Rapid heartbeat
- Slowed or stopped breathing
- Drowsiness
- Mental Confusion
- Dependence

The public health risks to well-known mu-opioid receptor agonists, such as heroin and fentanyl, are well established and have resulted in large numbers of drug treatment admissions, ER visits, hospitalizations, and fatal overdoses. Thus, it follows that tianeptine poses the same or similar risks. It also poses a greater risk because it is unknown how to best counter the effects since it is unregulated and not tested in Florida's laboratories. Naloxone may be effective to combat an overdose, but tianeptine affects other brain receptors, potentially limiting its effectiveness. Tianeptine dependence during pregnancy has also been linked to neonatal abstinence syndrome mimicking opioid neonatal abstinence syndrome. The true extent and exposure of tianeptine continues to unfold as more information becomes available.

The lack of national reporting on tianeptine has not slowed down its increasing impact on the country. Cases continue to rise as the public turns to this easily accessible drug marketed online as an opioid alternative and treatment for anxiety and depression. This causes a heightened risk for those with a history of opioid use disorder or dependency. Accordingly, it is obvious that if tianeptine continues to make headway in Florida, it will pose a significant public health risk to all Floridians and its many visitors.

CONCLUSION

Tianeptine has been designated as Schedule I controlled substances by Ohio, Georgia, Kentucky, Minnesota, and Indiana. Alabama has designated it as a Schedule II controlled substance. Given the history and current pattern of abuse of this "gas station heroin" detailed above, I believe it is reasonable to assume that there is a substantial likelihood that abuse of tianeptine will continue to take place in Florida, additional deaths are likely, and that the abuse of this substance will not be contained to specific locations or geographic regions. The rapid increase of abuse of this opioid-like drug causes extreme public health concern due to its contribution to the current opioid epidemic.

History demonstrates that one of the most effective means of curtailing abuse of dangerous addictive substances is to designate them as controlled substances under the law and provide felony penalties for those who illegally manufacture, distribute, sell, or possess them. Law enforcement authorities will then have the essential legal tool they need – a felony charge – to arrest, prosecute, and incarcerate persons who manufacture and peddle these dangerous substances.

Designation of tianeptine as a Schedule I controlled substance under the Florida Comprehensive Drug Abuse Prevention and Control Act will temporarily allow our law enforcement agencies to act against manufacturers and vendors until the completion of the 2024 legislative session.

Hereby ORDERED this 20<sup>th</sup> day of September, 2023.

  
ASHLEY MOODY  
ATTORNEY GENERAL

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<sup>1</sup> Florida Fusion Center, 7/26/2023, Bulletin, Product # 23-079.

<sup>2 3</sup> DEA-DCI-BUL-061-23

THE FULL TEXT OF THE EMERGENCY RULE IS:

2ER23-1 Addition of TIANEPTINE (7-((3-chloro-6-methyl-5,5-dioxido-6,11-dihydrodibenzo[c,f][1,2]thiazepine-11-yl)amino)heptanoic acid TO SCHEDULE I, SUBSECTION 893.03(1)(a), F.S.

Rulemaking Authority 893.035, F.S., Law Implemented 893.03, 893.035, F.S. History – New .

THIS RULE TAKES EFFECT IMMEDIATELY UPON BEING FILED WITH THE DEPARTMENT OF STATE  
UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.

EFFECTIVE DATE: September 20, 2023