

Congress of the United States

Washington, DC 20515

January 18, 2024

Dr. Robert Califf
Commissioner
U.S. Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write to request information about the Food and Drug Administration's actions to address tianeptine use. Tianeptine, which is commonly known as "gas station heroin" and sold under brand names like Zaza and Tianna, has opioid-like qualities and is extremely addictive.¹ We urge the FDA to take immediate action to research and provide guidance on tianeptine use.

Tianeptine is a tricyclic antidepressant that binds to mu-opioid receptors in neurons, the same sites where opioids such as oxycodone bind.² While tianeptine is approved for pharmacological use in several European, Latin American, and Asian countries, it has never been approved by the FDA for medical use in the United States. Although tianeptine is not approved for any medical use through the FDA, nor currently scheduled under the Controlled Substances Act (CSA) and regulated by the Drug Enforcement Agency (DEA), it is widely available for purchase.

Recent reporting indicates that tianeptine is extremely addictive and that tianeptine withdrawal symptoms are strikingly similar to opioid withdrawal symptoms, including nausea, chills, and insomnia.³ Recent medical research indicates that tianeptine can cause fatal overdoses.⁴ Several states, including Alabama, Michigan, Mississippi, Tennessee, Georgia, Indiana, Ohio, Florida, and Kentucky have taken action to ban or strictly control tianeptine sales at the state level.⁵

The FDA first issued a warning on tianeptine use in 2018, noting that users may "inadvertently find themselves addicted to tianeptine and should avoid all products containing this ingredient."⁶ Your agency issued an additional warning in 2022, warning that reports indicate that "tianeptine has a potential for abuse."⁷ And in November 2023, FDA issued a warning for consumers not to purchase or use any products sold under the brand Neptune's Fix that contain tianeptine after reports of severe adverse events by users including seizures and hospitalizations.⁸ While we

¹ <https://www.uab.edu/reporter/outreach/uab-in-the-community/item/9574-toxicologist-unravels-the-dangerous-medic-al-mystery-of-zaza-alabama-s-gas-station-dope>

² https://www.deaddiversion.usdoj.gov/drug_chem_info/tianeptine.pdf

³ <https://www.vice.com/en/article/dy3vvq/gas-station-heroin-tianeptine-zaza-pills>

⁴ <https://academic.oup.com/jat/article/42/7/503/4939213>

⁵ <https://www.forbes.com/sites/tylerroush/2023/03/24/growing-danger-of-gas-station-heroin-kentucky-latest-state-to-ban-tianeptine-opioid-like-drug-sold-in-groceries/?sh=236b18ae3f2c>

⁶ <https://www.fda.gov/food/cfsan-constituent-updates/fda-takes-action-products-marketed-dietary-supplements-containing-tianeptine-and-warns-consumers>

⁷ <https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death>

⁸ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-neptunes-fix-or-any->

appreciate these warnings, we believe that more action on tianeptine use is needed to ensure the health and well-being of the American people.

To that end, we respectfully request answers to the following questions, along with supporting documentation, as soon as possible.

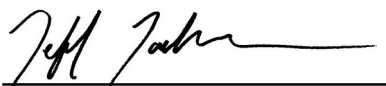
What actions has the FDA taken to provide oversight of tianeptine besides the 2018, 2022, and 2023 warnings?

1. What research is the FDA engaged in to determine the pharmacological properties of Tianeptine?
2. What are the effects of regular or over usage of tianeptine use on human health?
3. What ways, if any, is the FDA working with federal and state law enforcement, public health agencies, and advocacy groups to better understand the marketing and distribution of Tianeptine and its effect on public health?
4. Has the FDA taken any steps in conjunction with DEA to research whether tianeptine should be scheduled under the Controlled Substance Act?

The urgent need for FDA action on tianeptine cannot be overstated. It is vital to support legislative or administrative initiatives that strengthen FDA oversight and provide states greater ability to protect our communities from the dangers posed by substances like tianeptine.

We look forward to hearing from you on this pressing matter.

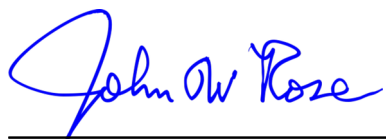
Sincerely,



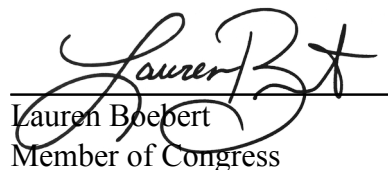
Jeff Jackson
Member of Congress



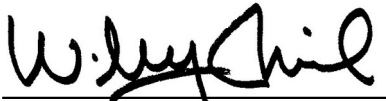
Rich McCormick, MD, MBA
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