



January 11, 2024

To Whom it May Concern:

The U.S. Food and Drug Administration (FDA) issued a public safety alert on November 21, 2023, after receiving multiple reports of serious medical injuries related to “Neptune’s Fix.” Neptune’s Fix is labeled to contain the dangerous and addictive ingredient tianeptine. Tianeptine is not approved for any medical use in the United States and is often unlawfully labeled or sold as a dietary supplement. FDA continues to receive reports of consumers who have suffered seizures, loss of consciousness or other adverse health events after ingesting this product. **We are reaching out because most consumers report purchasing this product at local gas stations or convenience stores across the country.**



FDA is urging all retailers to STOP selling Neptune’s Fix and any tianeptine-containing products. We are asking that trade associations please share the message above and information below to keep consumers safe:

- FDA warns consumers not to purchase or use Neptune’s Fix or any tianeptine product due to serious risks: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-neptunes-fix-or-any-tianeptine-product-due-serious-risks>
- Tianeptine Products Linked to Serious Harm, Overdoses, Death: <https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death>

Further, FDA is actively investigating new reports in conjunction with local and state health departments. We are also aware that Neptune’s Fix and other tianeptine-containing products are sold illegally online and in other retail locations. At least twelve states have banned the sale of tianeptine.



According to the [CDC](#), the clinical effects of tianeptine abuse and withdrawal can mimic opioid toxicity/withdrawal.

Consumers and retailers should report adverse events or side effects related to the use of Neptune's Fix and similar products to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at [MedWatch Online Voluntary Reporting Form](#), or;
- Download and complete the [form](#), then submit it via fax at 1-800-FDA-0178.

Please respond to this email for any additional information or clarification.

Sincerely,

Health Fraud Branch
Office of Regulatory Affairs
U.S. Food and Drug Administration
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