U.S. FOOD & DRUG ADMINISTRATION

Urgent Message from the U.S. Food & Drug Administration – Recalled Neptune's Fix products

January 31, 2024

To Whom It May Concern:

On January 11, 2024, the U.S. Food and Drug Administration (FDA) reached out to your organization about a public health matter involving a product, Neptune's Fix, which has been the subject of multiple reports of serious medical injuries, including death. Neptune's Fix products are labeled to contain the dangerous and addictive ingredient tianeptine, which is not approved for any medical use in the United States.

On January 28, 2024, the company responsible for Neptune's Fix products, Neptune Resources, LLC, issued a voluntary nationwide recall of all Neptune's Fix products – Neptune's Fix Elixir, Neptune's Fix Extra Strength Elixir, and Neptune's Fix Tablets.

We are reaching out again as most consumers report purchasing this product at gas stations or convenience stores across the country. We urge you to spread this recall announcement with your members to keep consumers safe and so your members can take appropriate steps should they have any Neptune's Fix products in their possession.

FDA is investigating new Neptune's Fix reports in conjunction with state and local partners. The agency has warned 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

To-date, eleven states have designated tianeptine as a controlled substance (i.e., Schedule I or Schedule II): Alabama, Florida, Georgia, Indiana, Kentucky, Michigan, Minnesota, Mississippi, Ohio, Oklahoma and Tennessee.

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 reply to this email for any additional information or clarification.

Sincerely,

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