

Subject: FDA Warns Illegal Marketers of Unproven Claims to Treat Opioid Use Disorder with Tianeptine-Containing Products

The [Food and Drug Administration](#) (FDA) issued [warning letters](#) to [Jack B Goods Outlet Store](#) for its Tianaa Red, Tianaa White, and Tianaa Green products and to [MA Labs](#) for its Vicaine product.¹ Both companies are marketing tianeptine-containing products as dietary supplements, and making unproven claims to treat opioid use disorder (OUD).

The Impact

Under the [Federal Food, Drug, and Cosmetic Act](#) (FFDCA), a dietary supplement containing tianeptine is adulterated since tianeptine is an unsafe additive. The FDA has not approved tianeptine for any indication, and using products which have not been proven to be safe and effective may prevent those addicted to opioids from seeking approved treatments and increase their risk of death.

The FDA reports tianeptine may cause significant adverse effects including neurologic, cardiovascular, and gastrointestinal symptoms. Some effects may resemble opioid toxicity or withdrawal. The [Centers for Disease Control and Prevention](#) (CDC) also [reported](#) in August 2018 that calls to [US Poison Control Centers](#) noting tianeptine exposure increased from 2014 to 2017.²

Any adverse effects related to these products should be reported through the [FDA Safety Reporting Portal](#).

For more information, please contact your Account Manager or Account Pharmacist.

¹<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626349.htm>

²<https://www.cdc.gov/mmwr/volumes/67/wr/mm6730a2.htm>