VIA ELECTRONIC MAIL
READ/DELIVERY RECEIPT REQUESTED

May 27, 2026

Gene Kakaulin
Chief Executive Officer
Curex, Inc. dba Curex
777 Brickell Ave #500-95053
Miami, FL 33131
gene@curex.org

Mr. Kakaulin:

FDA acknowledges receipt of your correspondence dated September 30, 2025, in which you responded to FDA's warning letter dated September 9, 2025.

Your letter describes a commitment to compliance and asserts that you have taken actions to address the compounded drug products offered for sale on your website that FDA identified as misbranded under sections 502(a) and 502(bb) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. §§ 352(a) and 352(bb)]. Such actions include "[i]mmediate content remediation," "[p]rominent disclosures," and "[g]overnance and prevention of recurrence."

Your response is partially adequate. Your response addresses some of FDA's concerns. For example, you state that you "systematically reviewed all webpages" and that certain identified "phrases (and any variants conveying the same message) have been removed everywhere on [your] site." However, FDA has identified shortcomings in your response that preclude finding the response fully adequate in light of sections 502(a) and 502(bb) of the FDCA [21 U.S.C. §§ 352(a) and 352(bb)], including the following:

- Your response relies on disclaimers, clarifications, contextualization, or disclosures as a means of addressing certain false or misleading claims. In your response, you state: "Where appropriate, content was replaced with language that…clearly states that compounded drugs are not FDA-approved" and that "each relevant page now states…that compounded drugs prepared by state-licensed 503A pharmacies are not FDA-approved...." An FDA review of your website in April 2026 identified examples of the statements described in your response, including: "Compounded medications have not been approved by the FDA and the FDA has not evaluated their safety or efficacy."

  Such statements do not, in this context, mitigate the misleading impression.

- FDA's review of your website in April 2026 indicates that, although you have made changes in response to previously identified issues, your reassessment of advertising and promotional materials was not comprehensive. For example:

1. Your response indicates that you have "removed comparative or 'same active ingredient' messaging and any language that could be interpreted as claims of interchangeability, sameness, or clinical equivalence to FDA-approved drugs." You also state you have "removed any language implying that compounded GLP-1 drugs are as effective and safe as FDA-approved drugs." However, compounded drug products continue to be offered for sale in a manner inconsistent with the corrective actions described in your response. For example, statements on your website, such as "[c]ompounded Tirzepatide (same active ingredient as Mounjaro®*)" and "Curex offers the same active ingredient as Mounjaro," continue to create the misleading impression that your compounded drug products are the same as, or equivalent to, the FDA-approved drug products.

2. Compounded drug products displayed on your website identify "Curex" on the pictured label, suggesting Curex is the compounder of those drug products when in fact it is not.[1]

The examples cited above do not constitute an all-inclusive list of inadequacies with your response or continued compliance concerns.

In support of your compliance efforts, please take into consideration that:

- As explained in the September 9, 2025, warning letter, you are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations, including that they are not misbranded under sections 502(a) and 502(bb) of the FDCA [21 U.S.C. §§ 352(a) and 352(bb)]. As described in the warning letter, claims and representations that are false or misleading with respect to efficacy or to risk can cause a compounded drug product to be misbranded. This can include representations made or suggested about benefit, as well as failure to reveal material facts (e.g., risk information).

- FDA has received complaints regarding your promotional materials for compounded drug products disseminated across multiple platforms, including your website. Additionally, FDA is generally aware of adverse event reports associated with compounded drug products. The existence of complaints and adverse event reports increases the concern about the public health implications of the promotional materials

[1] *See* 21 CFR § 201.1(h)(2) ("The appearance on a drug product label of a person's name without qualification is a representation that the named person is the sole manufacturer of the product. That representation is false and misleading, and the drug product is misbranded under section 502(a) of the act, if the person is not the manufacturer of the product in accordance with this section."); FDCA § 503(b) [21 § U.S.C. 353(b)], FDCA § 503B(a)(10)(A)(ii) [21 U.S.C. § 353b(a)(10)(A)(ii)]. We note that 21 CFR § 201.1(a) does not apply to drug products dispensed in accordance with section 503(b)(1) of the FDCA [21 USC § 353(b)(1)]. However, *see* 45 Fed. Reg. 25760, 25765 (Apr. 15, 1980) ("…if the label of a prescription drug product dispensed by a pharmacist does contain a representation as to the manufacturer, packer, or distributor, it must comply with all the provisions of § 201.1…."). In addition, the labels of your drug products as depicted on the website do not indicate that they are dispensed under section 503(b)(1) of the FDCA [21 USC § 353(b)(1)], nor do they appear to comply with the requirements of section 503(b)(2) [21 USC § 353(b)(2)].

remaining on your website that may mislead consumers about the regulatory status, safety, or efficacy of compounded drug products.

- FDA warning letters related to compounded drug products are available at the following website: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters. Warning letters addressing online advertising and promotion of compounded drugs can typically be identified by searching "telehealth."

FDA's evaluation of your operation remains ongoing and is not limited to your website. You are advised to reassess your advertisements and promotional materials across all platforms, including television and social media, and take immediate measures to address any violations within fifteen (15) working days from the date of this letter. Failure to adequately address any violations may result in legal action without further notice, including, without limitation, seizure and injunction.

To assist FDA in its ongoing evaluation of your operation, within fifteen (15) working days of receipt of this letter, please provide FDA with a list of entities that produce the compounded drug products offered on your website and a representative sample of labeling for such drug products.

Questions regarding the contents of this letter should be sent to compoundinginspections@fda.hhs.gov.

Sincerely,

Matthew J. Lash -S

Digitally signed by Matthew J. Lash -S
Date: 2026.05.27 10:09:56 -04'00'

Matthew J. Lash
Acting Director
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research