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September 30, 2025

George Tidmarsh, M.D., Ph.D.
Office of Compounding Quality and Compliance (OCQC)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

Delivered via email compoundinginspections@fda.hhs.gov.

Subject: Response to Warning Letter — Curex (dated September 9, 2025)

Dr Tidmarsh:

Curex acknowledges receipt of the FDA's Warning Letter dated September 9, 2025, regarding certain statements on our website related to compounded semaglutide and tirzepatide. We take these concerns seriously and have acted promptly.

Actions Completed

1) Immediate content remediation

- We systematically reviewed all webpages at getcurex.com where the cited and similar statements appeared.
- The following phrases (and any variants conveying the same message) have been removed everywhere on our site:
 - "Clinically proven success"
 - "Clinically proven weight loss treatments"
 - "The same active ingredients as Ozempic or Mounjaro"
 - "Prescription weight loss with the same active ingredients as Mounjaro & Zepbound."
 - "While we don't prescribe Ozempic, Wegovy, Zepbound, or Mounjaro directly, we may prescribe treatments containing the same active ingredients."

- Where appropriate, content was replaced with language that (i) avoids any implication of equivalence or sameness to FDA-approved products, (ii) clearly states that compounded drugs are not FDA-approved, and (iii) avoids efficacy or risk minimization claims.

2) Prominent disclosures now in place

- Each relevant page now states, in plain language, that compounded drugs prepared by state-licensed 503A pharmacies are not FDA-approved and are dispensed only pursuant to a patient-specific prescription.
- We 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.
- We have removed any language implying that compounded GLP-1 drugs are as effective and safe as FDA approved drugs.

3) Governance and prevention of recurrence

- Implemented a Regulatory Pre-Publication Checklist for all web copy touching on compounded medications, including explicit prohibition of comparative “same/similar to [brand]” phrasing and “clinically proven” efficacy claims unless supported and permitted.
- Established a two-person review/approval process (Medical + Regulatory/Compliance) for any new or revised web content related to compounded products.
- Conducted staff training (Marketing, Product, and Web teams) on FDA advertising and promotion requirements for compounded drugs.
- Created and will maintain a change log (with page URLs, edits, timestamps, approvers).

Please refer to **Exhibit A** for a list of all website edits made in response to your letter.

Ongoing Monitoring & Contact

We have trained our teams and will continue to monitor our website on a rolling basis to ensure continued compliance and to prevent re-emergence of cited claims.

Primary contact for this matter:

Gene Kakaulin, CEO
Curex, Inc.
777 Brickell Ave #500-95053, Miami, FL 33131
gene@curex.org
(212) 951-0720

We appreciate FDA's guidance and the opportunity to promptly address these concerns.

Sincerely,

Gene Kakaulin
CEO
Curex, Inc.

Exhibit A: Website Edits Made

Previous website copy	New website copy
Weight Loss	GLP-1
Clinically proven success	(Deleted)
Weight loss meds at unbeatable prices	GLP-1 medication at unbeatable prices
Prescription weight management treatment with compounded semaglutide or tirzepatide.	Personalized prescription GLP-1 medication, as injectables, tablets or drops.
Prescription weight loss with the same active ingredients as Ozempic & Wegovy	Personalized prescription GLP-1 medication
Prescription weight loss with the same active ingredients as Mounjaro & Zepbound	Personalized prescription GLP-1 medication
Clinically proven weight management treatments	Our GLP-1 injectables
Efficacy and convenience with oral dissolving tablets (ODT)	Our GLP-1 oral dissolving tablets (ODT)
GLP-1 drops: the same active ingredient at the lowest price	Our GLP-1 sublingual drops
Our weight management medication is delivered straight to your doorstep from a state-licensed pharmacy within our reliable network, ensuring you receive your medication when you need it.	Our GLP-1 medication is delivered straight to your doorstep from a state-licensed pharmacy within our reliable network, ensuring you receive your medication when you need it.
Weight loss treatment tailored to you	GLP-1 treatment tailored to you
Start your weight loss journey now	Start your GLP-1 journey now
What is compounded semaglutide? Semaglutide is the active ingredient in Ozempic®* and Wegovy®*. Compounded semaglutide refers to a version of the FDA-approved drug semaglutide that is custom-made by a compounding pharmacy. Compounded medications are made by state-licensed pharmacies that follow both federal and state regulations, including quality standards. However, these medications are	What is compounded semaglutide? Compounded semaglutide is custom-made by a compounding pharmacy. Compounded medications are made by state-licensed pharmacies that follow both federal and state regulations, including quality standards. However, these medications are not subject to FDA approval and are not evaluated for safety or effectiveness.

Previous website copy	New website copy
not subject to FDA approval and are not evaluated for safety or effectiveness.	
What is compounded tirzepatide? Tirzepatide is the active ingredient in Mounjaro®* and Zepbound®*. Compounded tirzepatide refers to a version of the FDA-approved drug tirzepatide that is custom-made by a compounding pharmacy. Compounded medications are made by state-licensed pharmacies that follow both federal and state regulations, including quality standards. However, these medications are not subject to FDA approval and are not evaluated for safety or effectiveness.	What is compounded tirzepatide? Compounded tirzepatide is custom-made by a compounding pharmacy. Compounded medications are made by state-licensed pharmacies that follow both federal and state regulations, including quality standards. However, these medications are not subject to FDA approval and are not evaluated for safety or effectiveness.
Same active ingredient as Ozempic®* & Wegovy®*	(Deleted)
Same active ingredient as Mounjaro® & Zepbound®*	(Deleted)
What medications do your providers prescribe? We prioritize a personalized approach to your health. If your medical provider prescribes medication, options may include GLP-1 treatments such as compounded tirzepatide (the active ingredient in Mounjaro®* and Zepbound®*). Our providers prescribe only combination treatments not available at your local pharmacy that may include vitamin B12, etc. to help you achieve your goals faster. Depending on your treatment goals, other medications such as metformin may also be considered. We recognize the importance of managing side effects, so your care plan might include medication to ease symptoms like nausea. Your well-being is always our top priority! Please note that compounded medications are customized to meet individual patient needs and are not FDA-approved for safety	What medications do your providers prescribe? We prioritize a personalized approach to your health. If your medical provider prescribes medication, options may include GLP-1 treatments such as compounded semaglutide or tirzepatide. Our providers prescribe only combination treatments not available at your local pharmacy that may include vitamin B12, etc. to help you achieve your goals faster. Depending on your treatment goals, other medications such as metformin may also be considered. We recognize the importance of managing side effects, so your care plan might include medication to ease symptoms like nausea. Your well-being is always our top priority! Please note that compounded medications are customized to meet individual patient needs and are not FDA-approved for safety or effectiveness. A prescription is necessary.

Previous website copy	New website copy
or effectiveness. A prescription is necessary. Results may vary from person to person. Curex and its pharmacy partners do not have any association with Novo Nordisk.	Results may vary from person to person. Curex and its pharmacy partners do not have any association with Novo Nordisk or Eli Lilly.
Can you prescribe Ozempic®, Wegovy®, Zepbound® or Monjaro®? Our providers focus on personalized medications and dosages that aren't commercially available at your local pharmacy. While we don't prescribe Ozempic®, Wegovy®, Zepbound®, or Mounjaro® directly, we may prescribe treatments containing the same active ingredients. These medications are specially compounded for you by a licensed pharmacy to meet your specific needs.	Can you prescribe Ozempic®, Wegovy®, Zepbound® or Monjaro®? Our providers focus on personalized medications and dosages that aren't commercially available at your local pharmacy. We don't prescribe Ozempic®, Wegovy®, Zepbound®, or Mounjaro®. We may prescribe treatments containing compounded semaglutide or tirzepatide. These medications are specially compounded for you by a licensed pharmacy to meet your specific needs. Please note that compounded medications have not been evaluated by the FDA for efficacy and safety.
*Disclaimer: FDA-approved medications Ozempic® and Wegovy® are proprietary to Novo Nordisk®. FDA-approved medications Mounjaro® and Zepbound® are proprietary to Eli Lilly®. Curex is not affiliated with or endorsed by Novo Nordisk® or Eli Lilly® and we do not offer or supply these medications. If you are interested in these products, please consult your licensed healthcare provider or pharmacist. †In the STEP series of studies, semaglutide has been shown to result in an average weight loss of approximately 14.9% of body weight at a dose of 2.4 mg weekly over 68 weeks. In the SURMOUNT-1 trial, people using tirzepatide for weight management at doses of 5 mg, 10 mg, or 15 mg weekly achieved average weight loss of 15-22.5% of body weight over 72 weeks.	Disclaimer: FDA-approved medications Ozempic® and Wegovy® are proprietary to Novo Nordisk®. FDA-approved medications Mounjaro® and Zepbound® are proprietary to Eli Lilly®. Curex is not affiliated with or endorsed by Novo Nordisk® or Eli Lilly® and we do not offer or supply these medications. If you are interested in these products, please consult your licensed healthcare provider or pharmacist. Compounded medications have not been approved by the FDA and the FDA has not evaluated their safety or efficacy.

Previous website copy	New website copy
Compounded semaglutide and tirzepatide are offered based on the ongoing FDA Drug Shortage. For up to date information on drug shortage statuses, please visit: https://www.accessdata.fda.gov/scripts/drugs_hortages/. Compounded medications have not been approved by the FDA and the FDA has not evaluated their safety or efficacy.	