Curex, Inc.
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June 22, 2026

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

Delivered via email compoundinginspections@fda.hhs.gov.

Subject: Response to Warning Letter — Curex (dated May 27, 2026)

Dear Mr. Lash:

Curex, Inc. ("Curex") acknowledges receipt of FDA's letter dated May 27, 2026, which follows FDA's warning letter dated September 9, 2025 and our response dated September 30, 2025. We appreciate the Agency identifying the respects in which our prior remediation was incomplete, and we have treated those findings as a directive to conduct a comprehensive, site-wide reassessment rather than to address only the specific examples cited.

This letter describes (i) the comprehensive re-audit we conducted, (ii) the corrective actions taken, (iii) the process changes intended to prevent recurrence, and (iv) the materials FDA requested. A page-level remediation log is set out below. The 503A compounding pharmacies that fill the compounded semaglutide and tirzepatide products offered through our website are listed below, and representative sample labeling is provided as Exhibit A.

1. Comprehensive Reassessment Conducted

On receipt of the May 27, 2026 letter, we did not limit our review to the examples cited. We conducted a full review of getcurex.com covering both rendered page content and

the underlying page metadata — page titles, meta descriptions, and Open Graph / social-card tags — because several of the residual instances FDA identified, together with additional instances we found in our own review, resided in metadata that surfaces in search-engine results and social previews rather than in visible page body copy. This metadata layer was the principal gap in our September 2025 remediation, and it is now within the scope of our pre-publication review and monitoring.

Consistent with the Agency's instruction that our reassessment extend beyond the website, we also reviewed our promotional materials on other platforms, including paid search and social-media advertising and our email and SMS templates, and addressed comparative or equivalence language wherever identified.

2. Corrective Actions Completed

Our re-audit confirmed that, while most of the previously cited language had been removed, comparative "same active ingredient" and related claims remained in several locations — including page metadata and certain product-page titles — that our September 2025 remediation did not reach. We have corrected these. Specifically, we have:

- Removed the comparative "same active ingredient as Mounjaro®" and "same active ingredient as Zepbound®" constructions from the titles and visible copy of the compounded-tirzepatide product pages, which now use neutral descriptors.
- Removed superiority and efficacy-comparison framing (including "more effective" phrasing) from page titles and headings, and replaced "weight loss" promotional framing with neutral "GLP-1" and "compounded semaglutide or tirzepatide" descriptors.
- Removed the statement that we "may prescribe treatments containing the same active ingredient" and replaced it with a factual description that does not assert sameness or equivalence to any FDA-approved product.
- Updated page metadata — titles, meta descriptions, and Open Graph / social-card tags — so that comparative "same active ingredient" language no longer appears in search-result snippets or social previews.
- Retired the legacy /weightloss/ URL path on which several of these instances appeared; those URLs now redirect to remediated pages or return a 404 and are no longer reachable.

With respect to the Agency's specific finding under 21 CFR § 201.1(h)(2), we have reviewed our product imagery and confirmed that the labeling currently displayed and dispensed does not identify Curex as the manufacturer or compounder of the products. As reflected in Exhibit A, the labels identify the state-licensed 503A pharmacy that compounds each product (for example, "Compounded by: RPC2B, LLC"), and product imagery on the site no longer depicts labels that suggest Curex is the compounder.

We note FDA's point that disclaimers do not cure an otherwise misleading comparative claim. Accordingly, our approach has been to remove the misleading claims themselves rather than to rely on added disclaimer text to contextualize them.

Page-Level Remediation Log

The following log identifies the affected locations, the prior language, and the current remediated state. Each change is recorded in our internal change log with URLs, timestamps, and approvers.

Location	Prior language	Current (remediated) state
/glp1 (root) — title	"Compounded Tirzepatide: The More Effective GLP-1"	Neutral title; superiority / "more effective" framing removed.
/glp1/compounded-tirzepatide/3 — title	"(same active ingredient as Mounjaro®*)"	Page retired; URL no longer reachable.
/glp1/compounded-tirzepatide/2 & /4 — titles	"(same active ingredient as Mounjaro®*)" / "(same active ingredient as Zepbound®*)"	Retitled to neutral descriptors.
Product / FAQ body copy	"we may prescribe treatments containing the same active ingredient"	Replaced with factual description that does not assert sameness or equivalence.
/glp1b — meta description, Open Graph & social-card tags	"…The same active ingredients as Ozempic®* or Mounjaro®*."	Comparative "same active ingredients" language removed from all metadata.
Tirzepatide subpage meta descriptions	"Weight loss made easy. Prescription weight loss treatment…"	Replaced with neutral GLP-1 / compounded-medication framing.
Legacy /weightloss/ URL path	Hosted several comparative-claim pages	Path retired; URLs redirect to remediated pages or return 404.
Product imagery / labels	Could suggest Curex as compounder	Reviewed; imagery and labeling identify the 503A pharmacy as compounder (21 CFR § 201.1(h)(2)).

3. Process Changes to Prevent Recurrence

i. Expanded our pre-publication regulatory review to expressly cover page metadata (titles, meta descriptions, and Open Graph / social-card tags), which was the gap that allowed cited language to persist after the September 2025 remediation.

ii. Re-issued the Regulatory Pre-Publication Checklist to all relevant teams, with an explicit prohibition on "same active ingredient," sameness, equivalence, interchangeability, and comparative-efficacy claims, and conducted a focused training session for the Marketing, Product, and Web teams on the concerns raised in the May 27 letter.

iii. Implemented a recurring monthly review of all GLP-1 and compounded-medication pages — covering both rendered content and metadata — with findings recorded in a change log, and extended the same review discipline to our advertising and messaging templates on other platforms.

4. Response to FDA's Specific Requests

As requested in the May 27 letter, the state-licensed 503A compounding pharmacies that fill the compounded semaglutide and tirzepatide products offered through our website are:

- Innovation Compounding Pharmacy, LLC
- Boothwyn Pharmacy, LLC
- RPC2B, LLC
- Vios Compounding Pharmacy

Representative samples of current labeling for these compounded drug products are provided as Exhibit A. The labeling identifies the compounding pharmacy responsible for each product and does not identify Curex as the manufacturer or compounder. Should the Agency prefer these materials in a different format, or wish to receive additional labeling samples or documentation, please let us know and we will provide them promptly.

Ongoing Commitment

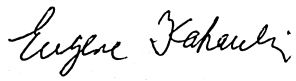
Curex remains committed to full compliance with the Federal Food, Drug, and Cosmetic Act. We will continue to monitor our website, advertising, and promotional materials across all platforms on an ongoing basis and to document our reviews. We welcome any further specific examples the Agency identifies and will address them promptly.

Primary contact for this matter:

Gene Kakaulin, CEO
Curex, Inc.
777 Brickell Ave #500-95053, Miami, FL 33131
gene@curex.org | Phone: (857) 240-1080

We appreciate the opportunity to promptly address these concerns and remain available to discuss any additional questions the Agency may have.

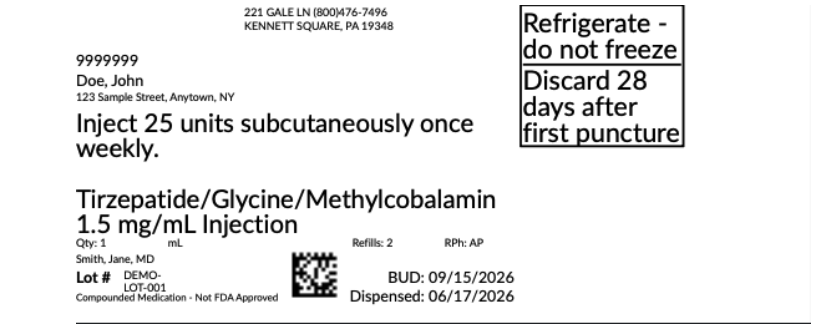
Sincerely,

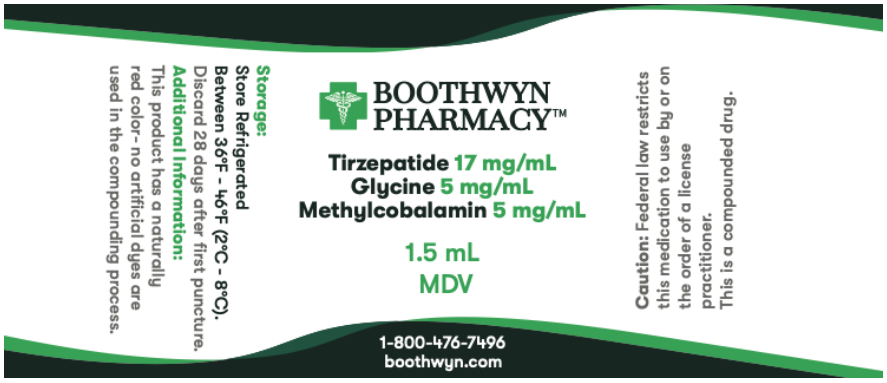


Gene Kakaulin
CEO
Curex, Inc.
gene@curex.org

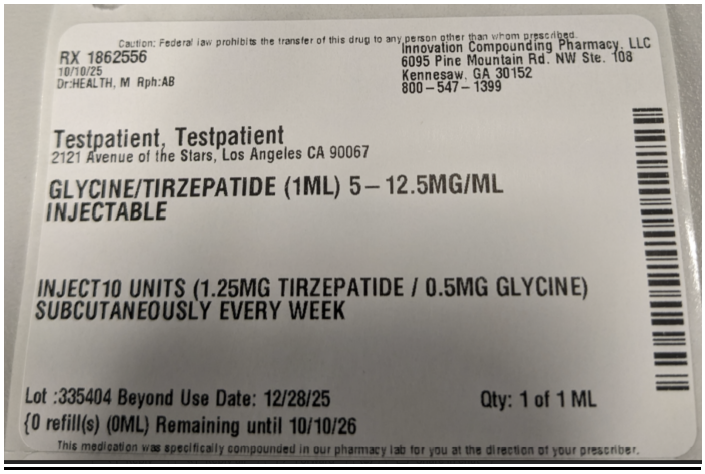
Exhibit A: Representative Labels of Compounded Products

Boothwyn Pharmacy, LLC





Innovation Compounding Pharmacy, LLC



RPC2B, LLC

Caution Federal Law Prohibits transfer of this drug to any person other than the patient for whom prescribed.

RX: 1[redacted] ORDER #: 5[redacted]

RX Written: 3/18/2026 Filled: 3/19/2026

[redacted]

RPh: Z.Jiang

[redacted]

RPC2B, LLC
61 E Willow St
Millburn, NJ 07041
(888) 852-2287

[redacted]

TIRZEPATIDE 80MG/ML SUBLINGUAL SUSPENSION - 5ML

Compounded by:
RPC2B, LLC

DRAW UP 0.15ML WITH SUPPLIED SYRINGE AND PLACE UNDER THE TONGUE DAILY. HOLD FOR 1 MINUTE BEFORE SWALLOWING.

QTY: 1

Lot #: T80-01 (1) Use by: 4/20/2026
Rx Exp: 3/18/2027 **0** refill(s) Remaining