

WARNING LETTER

Curex

MARCS-CMS 716821 — SEPTEMBER 09, 2025

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Delivery Method:

Via Electronic Mail - Delivery and Read Receipt Requested

Product:

Drugs

Recipient:

Curex

777 Brickell Ave #500-95053

Miami, FL 33131

United States

✉ hi@getcurex.com (<mailto:hi@getcurex.com>).

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

Feedback

WARNING LETTER

September 9, 2025

Curex:

This letter is to advise you that the United States Food and Drug Administration (FDA) reviewed your website content at the internet address <https://getcurex.com> in August 2025 and has observed that your website offers various compounded drug products, including semaglutide and tirzepatide.¹ As described below, your claims concerning compounded semaglutide and tirzepatide products are false or misleading 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)], resulting in products being introduced or delivered for introduction into interstate commerce in violation of section 301(a) of the FDCA [21 U.S.C. § 331(a)].

Under section 502(a) of the FDCA [21 U.S.C. § 352(a)] a drug is misbranded if its labeling is false or misleading in any particular. Furthermore, under section 502(bb) of the FDCA [21 U.S.C. § 352(bb)], a compounded drug is misbranded if its advertising or promotion is false or misleading in any particular.

The following claims concerning compounded semaglutide and tirzepatide products appear on your website:

- “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.”

Compounded drug products are not FDA-approved. Your claims imply that your products are the same as an FDA-approved product when they are not. As a result, these claims are false or misleading and your products are therefore misbranded under sections 502(a) and 502(bb) of the FDCA [21 U.S.C. §§ 352(a) and (bb)].

The introduction or delivery for introduction into interstate commerce of these misbranded products is a prohibited act under section 301(a) of the FDCA [21 U.S.C. § 331(a)]. The claims identified in this letter put you on notice of our concerns but do not represent an exhaustive list of misbranding violations.²

For the reasons discussed above, your compounded semaglutide and tirzepatide products are misbranded drugs under sections 502(a) and 502(bb) of the FDCA [21 U.S.C. §§ 352(a) and 352(bb)], introduced or delivered for introduction into interstate commerce in violation of section 301(a) of the FDCA [21 U.S.C. § 331(a)]. Please be advised, the receipt in interstate commerce of misbranded drugs, and the delivery or proffered delivery thereof, is also a violation of section 301(c) of the FDCA [21 U.S.C. § 331(c)].

As previously stated, the violations cited in this letter are not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your operations comply with all requirements of federal law, including FDA regulations.

You should take immediate action to address any violations (including, for example, ceasing and desisting from using the language cited above that misbrands the product). Failure to adequately address any violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen (15) working days of receipt of this letter, please provide a written response to the Office of Compounding Quality and Compliance (OCQC) within the Center for Drug Evaluation and Research (CDER)’s Office of Compliance describing the specific steps you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within fifteen (15) working days, state the reason for the delay and the time within which you will do so.

If you are not located in the U.S., please note that products that appear to be misbranded may be detained or refused admission. We may advise the appropriate regulatory officials in the country from which you operate that your products referenced above appear to be misbranded drugs that cannot be legally sold to consumers in the U.S.

All correspondence should include a subject line that clearly identifies the submission as a Response to Warning Letter. If you have questions regarding the contents of this letter, please contact compoundinginspections@fda.hhs.gov.

Sincerely,

/S/

George Tidmarsh, M.D., Ph.D.

1 The semaglutide and tirzepatide products offered on your website are drugs within the meaning of section 201(g) of the FDCA [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. Further, they are “new drugs” within the meaning of section 201(p) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.

2 Overstatements of efficacy or minimization of risk are of particular concern and may constitute misbranding.

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