



Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852.

June 25, 2026

Re: Federal Docket No. FDA-2018-N-3240

“List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act.”

To Whom It May Concern:

The National Consumers League (NCL) is a private, nonprofit consumer education and advocacy organization founded in 1899. Since its beginning, the League has represented the voice of consumers on matters affecting social justice, consumer protection, and the wellbeing of the American public.

Thus, NCL has taken up the challenge of addressing the nation’s persistent and growing obesity crisis in the U.S. from a consumer lens. Moreover, as an organization that combats fraud in the marketplace, NCL became concerned in 2025 about the massive disinformation consumers receive about compounded GLP-1 (glucagon-like peptide 1) agonists from online telehealth companies, med spas, and illegal online pharmacies. Accordingly, the League launched a national anti-disinformation effort called the *Weight Truth* on May 1, 2025, to arm consumers with the facts about GLP-1 weight loss drugs and to urge regulators, including the Food and Drug Administration (FDA), to enforce existing consumer protection laws, take bad actors off the market, and regulate compounding practices more aggressively.

It is within this framework that the National Consumers League is pleased to be a voice for the nation’s consumers – and specifically the more than 100 million adult Americans now living with obesity¹ – by submitting comments supporting the FDA’s proposed rule to formally exclude the GLP-1 drugs semaglutide, tirzepatide, and liraglutide from the 503B Bulks List.

Simply put, it is NCL’s position that by issuing a formal determination of no medical or clinical need for continued mass compounding of GLP-1 weight loss drugs, the proposed rule represents a defining moment in combatting the epidemic of false and misleading claims about compounded GLP-1 drugs that are now marketed as being as safe and effective as the FDA-approved versions, only cheaper and easier to obtain. Additionally, by applying this determination to exclude the three GLP-1 drugs – semaglutide, tirzepatide, and liraglutide – from the 503B Bulks List, the FDA’s proposed rule, if implemented, will improve patient safety by reducing the availability of mass-produced compounded GLP-1 drugs that were never intended to be marketed permanently. The following factors support NCL’s positions and underscore the importance of finalizing the proposed rule to help ensure the safe use of GLP-1 drugs.

¹ Stierman B, Afful J, Carroll MD, et al. [National Health and Nutrition Examination Survey 2017–March 2020 prepandemic data files development of files and prevalence estimates for selected health outcomes](#). *Natl Health Stat Report*. 2021;158.

FDA-Approved GLP-1 Weight Loss Drugs Require Medical Oversight and Prescribing Based on Eligibility Requirements and Contraindications

To date, the FDA has approved three GLP-1 agonists - semaglutide, tirzepatide, and liraglutide – for the treatment of obesity with defined eligibility criteria based on a body of data demonstrating the safety and effectiveness of these drugs in achieving weight reductions of 5 percent to 18 percent in clinical trials.² In addition, there is growing consensus that GLP-1 medications offer broader health benefits, such as reduced cardiovascular events, with the potential to markedly improve population health.

Accordingly, leading medical bodies – including the American Medical Association (AMA),³ the American College of Lifestyle Medicine (ACLM)² and American Society for Nutrition (ASN)² - support the use of GLP-1 medications for obesity treatment. Similarly, a number of medical societies, including the Obesity Medicine Association (OMA),² The Obesity Society (TOS),² the American Association of Clinical Endocrinology (AACE),⁴ and the Endocrine Society⁵ have published treatment guidelines for chronic weight management where GLP-1 drugs are prescribed as part of a comprehensive, long-term approach that also includes healthy diet, physical activity, and behavioral therapy.

However, clinical practice guidelines also reflect the fact that GLP-1 drugs are powerful prescription medicines requiring medical supervision due to significant side effects, complications, and the need to identify patients who are contraindicated for treatment, such as individuals with gallbladder disease, severe gastrointestinal conditions, kidney disease, and a history of certain thyroid cancers or pancreatitis. Thus, as a prerequisite for marketing each FDA-approved GLP-1 weight loss drug, the FDA requires a detailed label so healthcare providers will have the needed information about eligibility criteria, indications and usages, dosage and administration, dosage forms and strengths, and detailed warnings to ensure safe use.

This is not the case for compounded GLP-1 drugs, which, due to a different regulatory framework, are not required to obtain FDA approval or have a detailed label. Because this creates a Russian roulette situation for both health professionals and patients, both medical authorities and the FDA strongly caution that substituting a compounded GLP-1 version for an approved GLP-1 weight loss drug can be risky for patients. Therefore, NCL sees the prospect of a formal determination of no clinical need for compounded semaglutide, tirzepatide, and liraglutide changing health professionals' attitudes about recommending compounded GLP-1s and more HCPs following medical treatment guidelines.

Compounded GLP-1s Are Not as Safe as the FDA-Approved Medicines.

In February 2025, NCL took the unusual step of issuing a national alert to relay the FDA's warning to consumers and health professionals that unapproved compounded GLP-1 weight loss drugs are not required to disclose safety risks and "may contain the wrong ingredient or no active ingredient at all, or they may contain too much or too little of the active ingredient."⁶ A year later, on February 4, 2026, NCL issued a second alert, this time cautioning that "personalized" GLP-1s mixed with additives like vitamins and compounded products with different strengths and doses, such as microdosing, have not been tested for

² Mozaffarian D, et al. Nutritional priorities to support GLP-1 therapy for obesity: A joint Advisory from the American College of Lifestyle Medicine, the American Society for Nutrition, the Obesity Medicine Association, and The Obesity Society. *Obesity*. 2025 May 30;33(8):1475–1503

³ AMA Statement. November 6, 2025. AMA applauds administration for efforts to lower weight loss drug prices.

⁴ Samson SL, et al. American Association of Clinical Endocrinology Consensus Statement. Algorithm for Management of Adults with Type 2 Diabetes – 2026 Update. *AACE Clinical Guidance*, Volume 32, Issue 4p 473-518. April 2026.

⁵ Blog. "Society Invites People Living with Obesity to Help Shape Upcoming Obesity GPG." *Patient Perspectives on Medical Treatment of Obesity*. February 2, 2026. Accessible at: <https://www.endocrine.org/news-and-advocacy/blog-endocrine-signals/blog-february-2026>

⁶ Food and Drug Administration. "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss." U.S. Food and Drug Administration, December 18, 2024.

safety or effectiveness in clinical trials. With microdosing, there is the potential for the dose to be too low for a therapeutic benefit, and for side effects like dizziness and unforeseen complications, particularly for individuals with undiagnosed health conditions.⁷ Moreover, a recent study found that mixing tirzepatide with Vitamin B-12 generated impurities with unknown health impacts on patients.⁸

Collectively, these safety concerns translate into real-world harm for patients. While the lack of monitoring of compounded GLP-1s makes it difficult to know the extent of the problem, since 2022, compounding pharmacies and outsourcing facilities have accounted for a notable share of the recalls reported by the FDA Recall Dashboard, due to problems such as lack of sterility, incorrect potency, or contamination. Additionally, a 2018-2024 FAERS database analysis indicated that compounded GLP-1s carry significantly higher safety risks and quality issues than their non-compounded counterparts,⁹ which is reinforced by a study by researchers at Binghamton University who found that adverse events reported for compounded GLP-1s were nearly 2.5 times more likely to result in hospitalization compared to FDA-approved GLP-1 medicines.¹⁰

Due to these safety risks, there have been alarming reports of dosing errors, overdoses, and serious reactions to harmful ingredients in compounded GLP-1 products that the FDA has noted in a series of guidance documents. As of September 9, 2025, the FDA received 1,424 reports of adverse events linked to compounded GLP-1 drugs, including reports of 329 hospitalizations, and 23 deaths.¹¹ Moreover, poison control centers have seen a nearly 1,500 percent increase in calls since 2019 related to overdose or side effects of injectable weight loss drugs and have managed 3,633 GLP-1 agonist related exposure cases as of April 30, 2025.¹²

Therefore, NCL joins with the patient safety community in urging the FDA to exclude semaglutide, liraglutide, and tirzepatide from the 503B bulks list, not only because the agency has found no clinical need for compounding these products, but also because less availability of these API will thwart the deceptive marketing of these unapproved medicines.

The Supply Chain for Compounded GLP-1 API Is Unreliable.

Adding to the risks for consumers, patient safety experts have warned that the source of the active pharmaceutical ingredients (API) used in compounded GLP-1s is often from China, where quality standards can vary widely, and the API may go uninspected. According to a 2025 analysis by the Brookings Institution, less than a quarter of Chinese facilities marketing bulk quantities of the GLP-1 drug semaglutide had been inspected since they began marketing the product.¹³ The safety implications of foreign API importation should not be understated. Customs data shows that some of these shipments contain “research only” API, meaning that the product has not been purified to pharmaceutical grade.¹⁰ Additionally, there are many reports of shipments containing GLP-1 API that were not sterile or that were marked for use in an untested

⁷ Goodacre, S. “[The Benefits and Risks of Microdosing GLP-1s - EVEXIAS Health Solutions](#).” EVEXIAS Health Solutions, 2025.

⁸ B. Jordan et al., “A Novel, Widespread Impurity in Mass-Compounded Tirzepatide/B12 Products: Potential Patient Safety Implications,” *Expert*

⁹ Food and Drug Administration. FDA Adverse Events Reporting System Public Dashboard, data on compounded September 9, 2025

¹⁰ McCall KL, et al., Safety Analysis of compounded GLP-1 receptor agonists: a pharmacovigilance study using the FDA adverse event reporting system, (Apr. 29, 2025)

¹¹ National Consumers League petition to the Federal Trade Commission for an Investigation and Enforcement Action Against Online Telehealth Platforms Marketing Compounded GLP-1 Drugs and Fakes. September 22, 2025.

¹² America’s Poison Centers. “America’s Poison Centers - GLP-1,” 2025.

¹³ Wosińska, ME. “The Wild East of Semaglutide.” Brookings, April 21, 2025.

and unapproved product form, such as an ointment or for use in animals, even though there are no approved uses of GLP-1s in animals.

At the same time, demand for GLP-1s is fueling an unregulated parallel market producing finished medicines and API for U.S. buyers outside of the U.S. track-and-trace system. NCL is aware that compounded pharmacies have illegally obtained these drugs from unregistered facilities¹⁴ despite the FDA's establishment of the "Green List," increasing the likelihood that dangerous medications reach American patients.

Consumers Are Largely Unprotected from the Deceptive Marketing of Unapproved GLP-1 Weight Loss Drugs

Today a largely unregulated market is operating where telehealth platforms, med-spas and other sellers exploit gaps in the regulation of compounded drugs to promote the benefits of compounded GLP-1s through advertising practices that violate the Federal Trade Commission's prohibition against false and deceptive advertising. These practices include ads that expose consumers to unsubstantiated claims and misleading inferences regarding the comparable safety, efficacy, and ingredients used in compounded GLP-1 products.

This marketplace is a national threat due to the extent of the false information circulating online. Underscoring the challenge, a 2024 report from LegitScript found a 1,200 percent increase in violative or problematic" GLP-1-related ads between 2022 and 2024 that misled and "potentially endangered unsuspecting consumers."¹⁵ Similarly, a 2025 study of 79 websites selling compounded GLP-1s published in the *JAMA Health Forum* found alarming levels of misleading information that deceived consumers into believing that compounded GLP-1s are safe and effective, FDA-approved or generic versions of FDA approved drugs.¹⁶ But, what is especially alarming is that consumers believe these misleading claims. A national survey of 1,500 US women conducted for NCL in March found that 71 percent on those polled believe falsely that compounded drugs must be tested and proven safe to be on the market while 53 percent wrongly think that compounded versions are FDA-approved.

Now, the same regulatory loopholes that enabled the mass marketing of compounded GLP-1s are fueling a lucrative underground market—a legal and regulatory gray zone—in which sellers promote experimental GLP-1 drugs and untested peptides, as "research-grade" compounds not intended for human consumption. Participants in this market often dismiss the need for FDA-approved medicines, but that doesn't make their choices safe: according to CBS, reports of retatrutide exposure to America's Poison Centers shot up 265 percent since September 2025, with consumers experiencing serious adverse effects.¹⁷ A culture in which people inject themselves with untested substances is fundamentally dangerous.

The Price of Compounded Drugs Is Not an Argument for Allowing Less Safe Medications to Be Mass Marketed

As a national consumer organization, NCL believes that cost should never be a barrier to safe and effective obesity treatment. Thus, our organization welcomed the efforts by the Trump Administration to negotiate significant reductions in the price of FDA-approved GLP-1 drugs, which now cost self-pay patients (without insurance), between \$149 to \$299 per month for the new GLP-1 pill and start at \$199 a month for the injectable versions.

¹⁴ US. Food and Drug Administration, "[ProRx, LLC MARCS-CMS 696742 — March 04, 2025](#)," Warning Letter, March 4, 2025.

¹⁵ LegitScript. "LegitScript's Data Reveals 1200% Increase in Violative and Problematic Advertisements for GLP-1 Medications." LegitScript, July 16, 2024.

¹⁶ Chetty, Ashwin K, Mahima Chillakanti, Reshma Ramachandran, et al. "Online Advertising of Compounded Glucagon-like Peptide-1 Receptor Agonists." *JAMA Health Forum* 6, no. 1 (January 17, 2025).

¹⁷ "[This Weight-Loss Drug Hasn't Been Approved by the FDA: Doctors Are Prescribing It Anyway](#)," CBS News, June 8, 2026.

Opponents of the proposed rule continue to quote prices from before 2025 to contend that excluding the three GLP-1 drugs from the 503B Bulks List will eliminate an affordable alternative for patients who cannot pay the \$1,000+ monthly cost of brand-name GLP-1s. However, due to the change in pricing described above, this argument is now specious and does not reflect the findings of a September 2025 report from the Institute for Clinical and Economic Review (ICER), which concluded that GLP-1 drugs are cost-effective.¹⁸

Yet, of much greater importance for the health of consumers taking GLP-1s, the FDA does not approve drugs based on their cost or affordability. Thus, the agency should not condone the marketing of cheaper unapproved drugs “for which the FDA cannot verify quality, safety, or efficacy.” The alarming reports of dosing errors, overdoses, and serious reactions to harmful ingredients in compounded GLP-1 products is evidence that price should not be a factor when implementing rules affecting patient safety.

Conclusion

As described by FDA in its 2018 guidance for the compounding industry, compounded drug products serve an important role for patients whose needs cannot be met by an FDA-approved drug, such as those who need a medication to be modified because of an ingredient allergy or require a liquid form because they cannot swallow pills. However, today’s largely unregulated market allows telehealth platforms and other sellers to exploit gaps in compounded-drug regulation by promoting mass-produced compounded GLP-1s with unsubstantiated claims and misleading implications about their safety, efficacy, and ingredients.

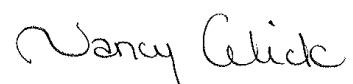
The consequences for consumers are so serious that NCL calls the exploitative market selling untested, unapproved GLP-1 drugs America’s second obesity crisis. Consumers navigating in this market are exposed to potentially unsafe drugs that are not tested or FDA-reviewed and many experience dosing errors, overdoses, and serious reactions to harmful ingredients as a result. And now, consumers are being enticed by deceptive marketing to opt for compounded products with added ingredients like Vitamin B-12; drugs in different strengths and doses such as microdosing; and products with different routes of administration, such as sublingual or buccal, than the forms FDA approved. All these developments are dangerous, as is an unreliable API supply chain and the proliferation of a dangerous gray market in which sellers promote experimental GLP-1 drugs and untested peptides as “research-grade” compounds not intended for human consumption.

FDA’s proposed rule, if implemented, could mark a major step in confronting this crisis, starting with a formal determination of no medical or clinical need for continued mass compounding of GLP-1 weight loss drugs. Moreover, the exclusion of semaglutide, liraglutide, and tirzepatide from the 503B bulks list will reduce the availability of mass produced compounded GLP-1 drugs that were never intended to be marketed permanently, including untested alterations or combinations that may endanger patients who take them. For these reasons, the National Consumers League applauds FDA for issuing the proposed rule to exclude the three GLP-1 drugs from the 503B bulks list and urges the agency to finalize and implement this rule on an expedited basis. The health and safety of many consumers will improve as a result.

¹⁸ Pearson SD, et al. Affordable Access to GLP-1 Obesity Medications: Strategies to Guide Market Action and Policy Solutions. April 9, 2025. Accessible at: <https://icer.org/wp-content/uploads/2025/04/Affordable-Access-to-GLP-1-Obesity-Medications--ICER-White-Paper--04.09.2025.pdf>

Thank you in advance for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script that reads "Nancy Glick".

Nancy Glick, Director, Food & Nutrition Policy
National Consumers League

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