June 29, 2026

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

Re: Comment in Support of FDA's 503B "Clinical Need" List Determination. Docket # FDA-2018-N-3240-0377

Executive Summary: Compounded GLP-1 products sold through online pharmacies, telehealth platforms, and social media channels pose serious and growing risks to American patients, intensified by widespread consumer misunderstanding of these products' regulatory status and safety. The evidence is unambiguous: patients are being deceived about what they are receiving, the supply chains behind these products lack meaningful oversight, prescribing practices on online platforms fall short of clinical standards, and enforcement actions document a market that is actively evading regulatory safeguards.

The Alliance for Safe Online Pharmacies (ASOP Global; www.buysaferx.pharmacy) urges the FDA to finalize its proposal to reject the nominations of semaglutide, tirzepatide, and liraglutide for inclusion on the 503B Bulks List. There is no clinical need to compound these products from bulk drug substances, and granting these nominations would expand a market that is already causing documented patient harm. Finalizing this proposal will protect patients, reinforce the integrity of the drug approval process, and ensure that FDA-approved medicines remain the standard for patient care.

To Whom It May Concern:

The Alliance for Safe Online Pharmacies (ASOP Global) respectfully submits the following comments in support of the U.S. Food and Drug Administration's (FDA's) proposal to reject the nominations of semaglutide, tirzepatide, and liraglutide for inclusion on the list of bulk drug substances for which there is a clinical need under section 503B of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353b(a)(2)(A)(i) (the "503B Bulks List").

ASOP Global is a nonprofit 501(c)(4) organization that seeks to protect patient safety globally and ensure access to safe, legitimate online pharmacies in accordance with applicable laws. ASOP Global is active in the United States, Canada, Europe, and Asia. ASOP Global submits this

comment due to the important connection between the 503B bulks-list nominations at issue and the growing availability of compounded drugs marketed and sold through online channels.

Patient Safety and Scientific Integrity

Patients face unnecessary risks from mass-produced "personalized" compounded products that lack demonstrated efficacy, meaningful adverse event reporting, and compliance with the Drug Supply Chain Security Act's product tracing requirements. The consequences of unsafe large-scale compounding are well-documented and growing. Since 2022, more than 600,000 compounded drugs have been recalled, including over 75,000 compounded GLP-1s, and regulators have uncovered serious problems at compounding facilities nationwide: unsanitary conditions, deficiencies in sterile drug preparation, use of illicit or non-pharmaceutical ingredients, and contamination with bacteria or endotoxins.[1] [2] [3] [4] [5]

This problem, combined with a flourishing online marketplace for unapproved drugs, where on-demand prescribing platforms sidestep clinical best practices, deprives patients of making informed health decisions. [6] What makes this especially dangerous is how little consumers understand the risks. ASOP Global Foundation's 2025 National Consumer Survey lays bare just how wide that knowledge gap is:

- More than a third of U.S. adults (38%) have purchased prescription medicines online – and of those, more than 1 in 4 (27%) report receiving substandard or counterfeit medicine, or being directly harmed by a product they bought. That's not a theoretical risk; it's harm millions of Americans have already experienced. [7]
- Yet 65% falsely believe all websites offering online prescription services are reviewed or approved by the FDA or state regulators –making patients less likely to question what they're buying or who they're buying it from. [8]

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[1] New York City Council Oversight and Investigations Division (2025). *Moving the Needle: A Joint Enforcement Operation Against Improperly Licensed Medspas in NYC*. Available at: https://council.nyc.gov/press/wp-content/uploads/sites/56/2025/12/OID_Medical_Spas-REPORT_120125-v847.pdf

[2] Ohio Board of Pharmacy (2025). *Ten Common Prescriber Clinic and Medical Spa Violations.* Available at: ten common prescriber clinic and medical spa violations.pdf

[3] FDA (2025). *FDA Adverse Event Monitoring System (AEMS) Public Dashboard.* Available at: https://www.fda.gov/drugs/fda-adverse-event-monitoring-system-aems/fda-adverse-event-monitoring-system-aems-public-dashboard

[4] McCall K. et al (2025). *Safety analysis of compounded GLP-1 receptor agonists: a pharmacovigilance study using the FDA adverse event reporting system.* Available at: https://pubmed.ncbi.nlm.nih.gov/40285721/

[5] State Board of Pharmacy regulatory and enforcement activities reported at National Association of Boards of Pharmacy Annual Meeting (2026), including actions by the Arizona, Ohio, Kansas, and Colorado Boards of Pharmacy

[6] Palmer, K. (2024). *How invisible medical groups are powering telehealth GLP-1 'gold rush'*, STAT. Available at: Telehealth's GLP-1 'gold rush' is powered by these medical groups

[7] ASOP Global Foundation. *2025 Consumer Behavior and Perception Survey*. Available at: ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf

[8] *Id*

- And 51% assume that only safe, verified sellers appear on the first page of search results, a false and dangerous belief. [9]

The gap between consumer perception and reality is especially stark when it comes to compounded GLP-1s marketed through online channels.

Among individuals currently taking GLP-1 drugs:

- 77% falsely believe compounded medications are evaluated by the FDA for safety and efficacy, a figure that climbs to 86% among those who actually obtain GLP-1s through an online provider. [10]

- Nearly half (46%) incorrectly believe compounded drugs are the same as generic medicines, rising to 57% among those who buy GLP-1s online. [11]

The real-world consequences from misperceptions, bad clinical practices, and unapproved drugs are already emerging. One study found higher odds of hospitalization and product-quality adverse events for compounded GLP-1s compared with their FDA-approved counterparts. Patients have begun sharing their stories publicly[12]:

- An Illinois man who became violently ill and was hospitalized; [13]

- A Kentucky woman who required an emergency liver transplant; [14]

- The family of a Texas mother who died after taking a compounded GLP-1 she didn't need. [15]

Given these gaps in understanding and the risks of an unregulated supply chain, the FDA's longstanding position, reaffirmed in this proposal: compounded products should be used only when a patient's medical needs cannot be met by an FDA-approved drug. At this time semaglutide, tirzepatide, and liraglutide are not in shortage, and compounded drugs should not be prescribed and dispensed at scale. [16]

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[9] *Id*
[10] *Id*
[11] *Id*
[12] McCall K. et al (2025). *Safety analysis of compounded GLP-1 receptor agonists: a pharmacovigilance study using the FDA adverse event reporting system.* Available at: https://pubmed.ncbi.nlm.nih.gov/40285721/
[13] Garcia, J. (2024). ABC 7 Eyewitness News. *Chicago man issues warning after taking fake Ozempic diabetes, weight loss drug*. Available at: https://abc7chicago.com/post/ozempic-weight-loss-diabetes-chicago-news-insulin/14268598/
[14] Meiner's A. (2026). WLKY. *'Jimmie's Law' provides stricter regulations on pharmaceutical compounding in Kentucky*. Available at: https://www.wlky.com/article/jimmies-law-stricter-regulations-pharmaceutical-compounding-kentucky/70503397
[15] Payne, M. Law 360 (2026), *Texas GLP-1 Compounder Caused Mom's Death, Family Says*. Available at: https://www.law360.com/articles/2464464/texas-glp-1-compounder-caused-mom-s-death-family-says
[16] Food and Drug Administration. (n.d.). Compounding and FDA: Questions and answers. U.S. Department of Health and Human Services. https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

The Online Pharmacy Nexus: Consumer Deception and Supply Chain Risk

The problem has drawn attention well beyond federal regulators. A bipartisan coalition of 38 state and territory attorneys general have warned that online retailers are illegally selling GLP-1 active ingredients directly to consumers without a prescription, targeting them through social media with promises of easier, more affordable access.[17] Those ingredients are sourced from unregulated, undisclosed suppliers in countries like China and India, introducing serious risks of contamination and adulteration that patients have no way to detect or verify. [18]

This opacity is by design. Online, undisclosed, obscured, or outright falsified sourcing is not the exception; it is the norm. Compounders may source active pharmaceutical ingredients from foreign manufacturers that have never been inspected by the FDA, leaving patients with no meaningful visibility into what they are actually receiving.

Since 2017, the FDA has issued a series of warning letters to API suppliers, including Enovachem, Vipor Chemicals, Spectrum Laboratory Products, Fagron, Lumis Global, and others, citing a consistent pattern of concealment: suppliers were hiding the true identity of the original API manufacturer on Certificates of Analysis, the very documents that customers and regulators rely on to verify the quality and origin of drug ingredients. When those documents are falsified, supply chain accountability disappears entirely, and patients bear the risk.[19]

Between 2022 and 2023, contaminated drug components led to more than 300 pediatric fatalities across at least seven countries, tragedies the FDA has directly linked to facilities that relied on Certificates of Analysis from suppliers with unverifiable chains of custody. [20] That is precisely the pattern playing out today in the compounded GLP-1 online market, at significant scale and with millions of consumers in the supply chain.

What makes this especially dangerous is that some compounders, telehealth platforms, and online drug sellers actively mislead consumers about the safety and efficacy of what they are selling. According to the National Association of Boards of Pharmacy, 96% of online drug sellers operate illegally, distributing products from foreign or unlicensed sources, without valid

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[17] National Association of Attorneys General (2025) *State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs*, NAAG. Washington, D.C., 19 February. Available at: https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/

[18] *Id*

[19] FDA Warning Letters to: Asclemed USA Inc. dba Enovachem (June 11, 2019); Vipor Chemicals Private Ltd. (January 29, 2019); Spectrum Laboratory Products (June 4, 2019); Yino, Inc. (October 28, 2019); B & B Pharmaceuticals, Inc. (June 4, 2019); Fagron, Inc. (August 29, 2018); Lumis Global Pharmaceuticals Co. Ltd. (March 2, 2017); Sal Pharma (April 20, 2017); Huron Pharmaceuticals, Inc. (April 20, 2017); Suzhou Pharmaceutical Technology Co., Ltd. (January 6, 2017); CBSCHEM Limited (January 31, 2014). Available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

[20] WHO (2023) *WHO urges action to protect children from contaminated medicines*. Available at: https://www.who.int/news/item/23-01-2023-who-urges-action-to-protect-children-from-contaminated-medicines

prescriptions, or selling counterfeit and substandard medications.[21] In this internet environment, American patients have effectively become test subjects: exposed to unapproved drug combinations and novel modes of administration, and increasingly targeted with "for research use only" chemicals and do-it-yourself injection kits marketed as legitimate treatment options. [22] [23] [24]

Inadequate Prescribing Practices in Online Channels

Market surveillance completed by S-3 Research, a firm run by Dr. Tim Mackey, tracking and analyzing illegal sale of prescription drugs on social media platforms, has documented deeply inadequate prescribing workflows on telehealth platforms offering compounded GLP-1s. Many rely exclusively on generic online questionnaires, accepting self-reported height, weight, and health history with no in-person examination and no independent verification. Physician consultations are frequently optional, offered via email, text, or video but never required. Most troubling, researchers found that even the minimal identity verification these platforms claim to provide can be defeated using AI-generated fake identification documents, meaning there is effectively no reliable gatekeeping between a consumer and an unapproved compounded drug.

Social media has become a primary distribution channel for unapproved GLP-1s, operating largely beyond the reach of any regulatory oversight. Researchers from S-3 have collected approximately one million posts and comments across various platforms discussing GLP-1s, documenting profiles that openly sell and administer peptide "research" products directly to consumers. The online pharmacy market, the telehealth platform, and the social media feed have become a seamless pipeline, each reinforcing the others, and each moving patients further from legitimate medical care.

Conclusion

For the reasons set forth above, ASOP Global respectfully urges the FDA to finalize its proposal to reject the nominations of semaglutide, tirzepatide, and liraglutide for inclusion on the 503B Bulks List. The FDA's clinical-need framework is sound, its analysis is thorough, and the evidence overwhelmingly supports one conclusion: there is no clinical need to compound these products from bulk drug substances.

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[21] National Association of Boards of Pharmacy (2024). *RogueRx Activity Report: Injectable Weight Loss Drugs: How Illegal Online Drug Sellers are Taking Advantage of Patients.* Available at: https://nabp.pharmacy/wp-content/uploads/2024/04/RogueRx-Activity-Report-Injectable-Weight-Loss-Drugs-2024.pdf

[22] National Association of Boards of Pharmacy (2024). *RogueRx Activity Report: Injectable Weight Loss Drugs: How Illegal Online Drug Sellers are Taking Advantage of Patients.* Available at: https://nabp.pharmacy/wp-content/uploads/2024/04/RogueRx-Activity-Report-Injectable-Weight-Loss-Drugs-2024.pdf

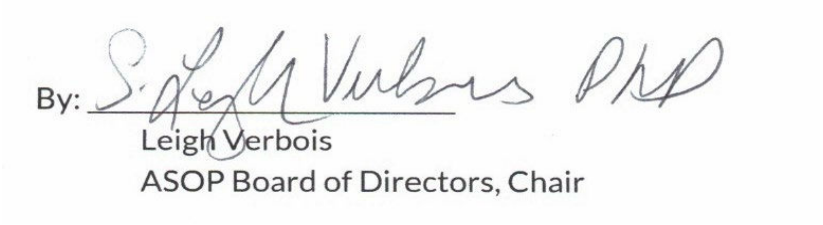
[23] National Association of Attorneys General (2025) *State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs*, NAAG. Washington, D.C., 19 February. Available at: https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/

[24] The New York Times, (2025). *Ozempic Fake Counterfeit Drugs*,vailable at: https://www.nytimes.com/2024/07/12/well/ozempic-fake-counterfeit-drugs.html?searchResultPosition=1

Finalizing this proposal will protect patients, reinforce the integrity of the drug approval process, and preserve the incentive framework that drives pharmaceutical innovation in the United States.

ASOP Global thanks the FDA for its leadership and its ongoing commitment to protecting Americans from unsafe and unapproved medicines. We look forward to continuing to work with the Agency in support of this public health mission. Should the FDA or its staff have any questions, please do not hesitate to contact ASOP Global anytime via Libby.Burstein@FaegreDrinker.com.

Respectfully submitted,



By: _____

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ASOP Board of Directors, Chair