July 16, 2026

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

Re: Docket No. FDA-2018-N-3240 – List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B

Americans for Safe and Effective Medicines (ASEM) supports the Food & Drug Administration's (FDA) proposal not to include semaglutide, tirzepatide, or liraglutide on the Section 503B Bulks List and urges the Agency to finalize that determination.

ASEM is a nonprofit consumer protection organization dedicated to advancing practical, evidence-based policies that protect patients, strengthen pharmaceutical supply chain integrity, and promote transparency in the prescription drug marketplace. Our work is grounded in a simple principle that patients deserve clear and accurate information about the medicines they use and confidence that those medicines meet appropriate standards of safety, quality, and oversight.

FDA's proposal reinforces those principles. Section 503B was created to ensure compounded medicines remain available when a patient's clinical needs cannot be met by an FDA-approved product—not to establish a commercial pathway for manufacturing copies of approved medicines.

Patient Safety & Consumer Understanding

Recent warning letters and actions by state and federal regulators have repeatedly documented marketing practices that blur these distinctions between FDA-approved medicines and compounded GLP-1 products. Patients are exposed to advertising that promotes compounded products as "personalized" and creates the false impression that compounded products offer comparable regulatory assurances.

ASEM's inaugural national survey reinforces why this distinction matters. Consumers overwhelmingly want medicines that have been rigorously reviewed, clinically tested, and independently evaluated, yet many mistakenly believe compounded GLP-1 products have those same safeguards. Consumer demand for compounded GLP-1 products appears to reflect misunderstanding about the regulatory status of those products, putting patients at risk. These findings suggest that demand for compounded products is driven, at least in part, by gaps in understanding about their regulatory status, emphasizing the need to close those gaps to protect patients and ensure informed treatment decisions.

Consumer Preferences & Market Misunderstanding

To better understand this disconnect, ASEM conducted national survey research among consumers, current GLP-1 users, and healthcare providers. The findings reveal:

- 84% of consumers say FDA approval, clinical testing, and independent expert review are important when choosing a GLP-1 medication. That number rises to roughly 90% among current GLP-1 users.
- Only 17% of consumers correctly understand that compounded GLP-1 products have not undergone the same FDA approval and clinical testing as FDA-approved medicines.
- Nearly half of current GLP-1 users mistakenly believe compounded GLP-1 products have gone through the same approval and testing process as FDA-approved therapies.
- More than 8 in 10 general medicine providers report encountering patients who are unaware that compounded GLP-1 products are not FDA-approved.

These findings reveal a significant disconnect between what consumers expect and what they understand. This distinction matters because consumer misunderstanding does not create clinical need. Section 503B asks whether an FDA-approved medicine can adequately meet a patient's medical needs, not whether consumers have been persuaded to seek a compounded alternative. When demand is driven by confusion about regulatory status rather than medical necessity, it cannot justify expanding the narrow exception Congress established for compounding.

Mass Personalization is Not Clinical Need

ASEM is particularly concerned about the growing use of standardized dosage adjustments, added vitamins, and other minor formulation changes marketed as personalization. While individualized compounding remains an important part of patient care, standardized modifications offered across large populations are fundamentally different from patient-specific treatment.

Patients deserve clarity about what individualized medicine is—and what it is not. Minor, medically unnecessary formulation changes should not be used to manufacture the appearance of patient-specific need, masquerade as individualized medicine, or circumvent the narrow limits Congress placed on compounding. Preserving that distinction protects patients by ensuring that compounding remains a patient-centered exception rather than routine commercial practice.

Conclusion

Patients deserve confidence that the medicines they receive are accurately represented, and that differences between FDA-approved medicines and compounded products are communicated clearly. In too many cases, marketing has become more sophisticated than disclosure. ASEM respectfully urges FDA to finalize its proposed determination not to include semaglutide, tirzepatide, or liraglutide on the Section 503B Bulks List. Doing so will reinforce Congress's intent that compounding remains a narrow exception for genuine clinical need, reduce marketplace confusion, strengthen consumer protections, and preserve the integrity of the FDA approval framework.

info@safeandeffectivemeds.org
www.safeandeffectivemeds.org
825 21st St NW, Unit 273
Washington, DC 20006