100 Daingerfield Road, Suite 100
Alexandria, VA 22314
www.a4pc.org

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

March 19, 2025

Dr. Sara Brenner
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: Objection to FDA's Recent Statement on Compounded GLP-1 Adverse Events

Dear Dr. Brenner:

I write on behalf of the Alliance for Pharmacy Compounding to protest in the strongest terms the FDA's recent statement regarding unapproved GLP-1 drugs and adverse events. The statement, based on unverified reports from the FDA's Adverse Event Reporting System (FAERS), unfairly casts doubt on the integrity of compounding pharmacies and compounded GLP-1 medications while failing to acknowledge the inherent limitations of FAERS data. The statement is both inflammatory and misrepresentative.

The FAERS database webpage includes language alerting readers about its limitations: "While FAERS contains reports on a particular drug or biologic, this does not mean that the drug or biologic caused the adverse event. Importantly, the FAERS data by themselves are not an indicator of the safety profile of the drug or biologic." The inclusion of an adverse event in FAERS, then, does not establish causation, nor does it reflect the incidence rate of such events in relation to actual patient usage. Yet your statement leaves the distinct impression that a compounded drug was indeed the cause of the reported adverse events. Moreover, the FDA's statement fails to note whether the adverse events reported were associated with actual compounded GLP-1s prepared in a legitimate state-licensed pharmacy, as opposed to illicit substances acquired from bogus online "pharmacies." That distinction matters.

Given this context, it is deeply concerning that the FDA has chosen to highlight FAERS reports in a manner that suggests definitive risks associated with compounded GLP-1s without providing appropriate context about those reported adverse events. Nor does the agency apply the same scrutiny to FDA-approved versions of these medications. The selective application of concern disproportionately burdens compounding pharmacies and misleads the public – many of whom rely on compounded therapies to live normal lives.

Furthermore, the FDA's most recent statement follows a concerning pattern of inflammatory language by the agency regarding compounded medications – frequently implying heightened risks without also acknowledging the essential and proper role of compounded medications. The agency's role should be to ensure patient safety through balanced, evidence-based communication rather than issuing statements that may needlessly deter patients from accessing necessary medications tailored to their individual needs.

Compounded GLP-1s have played a critical role in serving patients in the prolonged shortages of the commercially available products or whose prescriber has judged they require customized formulations. The FDA's statements on this issue have not only undermined pharmacy compounding but also have risked driving patients toward unregulated sources of medication out of fear and misinformation.

The Alliance for Pharmacy Compounding urges the FDA to reconsider its public messaging on compounded GLP-1s and to apply the same level of diligence and transparency to its assessment of both compounded and FDA-approved versions of these drugs. We request a meeting with FDA leadership to discuss these concerns and to advocate for a more balanced and evidence-driven approach to your public communication on compounded medications moving forward.

We appreciate your attention to this matter and look forward to your response.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer