100 Daingerfield Rd, Suite 100
Alexandria, VA 22314

www.a4pc.org

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

February 9, 2026

The Honorable Martin A. Makary, MD, MPH
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Makary:

I write on behalf of the Alliance for Pharmacy Compounding (APC) in response to the FDA's February 6, 2026 statement announcing its intent to restrict GLP-1 active pharmaceutical ingredients (APIs) for non-FDA-approved compounded drugs and to intensify enforcement regarding misleading advertising.

Let me begin with appreciation: the FDA's elevated attention to patient safety, product integrity, and deceptive promotion in this space is warranted. APC supports strong oversight where it is grounded in law, evidence, and a clear understanding of where actual risk resides.

While agency statements reflect an effort to respond quickly to concerns, APC urges the FDA to slow the pace of enforcement actions to allow for full consideration of the facts, the clinical realities facing patients, and the potential for unintended harm to patient access and continuity of care.

Prescriber judgment and patient-specific care
A foundational point in compounding done by state-licensed pharmacies is that nothing is prepared until a licensed provider determines, through individualized medical judgment, that a specific patient needs a specific compounded therapy and writes a prescription accordingly. State-licensed pharmacies do not independently choose therapies or clinical indications. Prescriber judgment is determinative. APC is therefore seriously concerned about any federal enforcement approach that may, in practice, interfere with lawful provider discretion in prescribing drugs using API authorized in law and policy — medical judgment that federal law has long recognized in patient-specific care.

To be clear, APC fully supports current law and FDA guidance that require, for exemption from the prohibition on compounding essentially a copy of a commercially available drug, that the drug be on the FDA's shortage list or that a prescriber determine and document a significant difference for the individual patient.

Several elements of the FDA's recent public messaging and warning-letter posture also raise substantial concerns.

Use of API that is a component of an FDA-approved drug
The FDA has previously recognized a core legal fact under the Federal Food, Drug, and Cosmetic Act: pharmacies may use bulk drug substances when those substances are components of FDA-approved drugs. FDA's own prior GLP-1 communications drew this distinction clearly, including in statements differentiating semaglutide base from semaglutide salts. That distinction matters. It reflects statutory criteria, not marketing language. If a bulk substance were not the applicable active ingredient component of an approved drug under the Act's framework, it would not be lawful for routine compounding use in the first place. Heretofore, the FDA has raised no concerns about quality of GLP-1 API from FDA-registered facilities that it deems to be cGMP compliant.

Truthful statements about active ingredient identity
Recent warning-letter language appears to take aim at pharmacies stating they use the same active ingredient as FDA-approved GLP-1 products. In many instances, that approach mischaracterizes factual reality. A truthful statement that a compounded preparation uses the same API as the approved reference product is not inherently false or misleading. It is, rather, simply accurate. What is impermissible – and APC agrees it is impermissible – is claiming FDA approval, therapeutic equivalence, or "generic" status where none exists.

Lawful pharmacy sourcing is not gray-market sourcing
The wording of the FDA's announcement seems to conflate legitimate, state-licensed pharmacy practice with unlawful gray-market activity. That is a fundamental error. Licensed pharmacies and FDA-registered outsourcing facilities do not source APIs from anonymous internet suppliers. They source through established, FDA-registered and inspected channels, with supporting documentation that commonly includes certificates of analysis and independent testing data. Enforcement aimed at lawful operators using lawful supply pathways will not solve the counterfeit crisis — it will instead reduce access for legitimate patients.

FDA's Green List and consistency in agency posture
The FDA's Green List framework, launched in 2025, confirmed an important point: not all foreign-made GLP-1 API is suspect, and FDA-registered manufacturers deemed acceptable under the FDA's quality framework are distinguishable from higher-risk sources. That framework acknowledged that quality-based differentiation is possible and appropriate. It should not now be blurred into rhetoric that implies broad illegitimacy of legally sourced API used by licensed pharmacies and outsourcing facilities. To put a fine point on it: any such blurring by the agency is contradictory to the agency's previous statements and actions.

Misleading advertising should be addressed
APC is clear on marketing practices: deceptive consumer-facing claims should be addressed. We have publicly urged responsible communications and developed APC's *Best Practices for Marketing Compounded Drugs* to help our member pharmacies align with law and policy. We are prepared to continue that work with the FDA, state boards of pharmacy, and other stakeholders.

Counterfeits and illicit sellers are the real threat
We must also be clear about the real threat. The gravest risk to patients is the flow of counterfeit and illicit substances entering the United States and being sold through bogus websites, social channels, and anonymous online forums. Those actors are not licensed pharmacies. They are criminals exploiting demand, confusing consumers, and undermining trust. A true crackdown should prioritize them. Thus far, though many have raised this concern — including state attorneys

general and members of Congress — we have seen no substantive focus on eradicating these illicit actors and instead continue to see illicit activity conflated with the essential work of legitimate state-licensed pharmacies.

APC remains committed to constructive engagement with the FDA, state regulators, prescribers, and policymakers. We support oversight that protects patients while preserving access to lawful, patient-specific compounded therapies that are, for many Americans, medically essential. *We urge the FDA to exercise enforcement discretion deliberately and in proper measure while unresolved policy questions remain under active review — and to avoid actions that unintentionally punish lawful pharmacy practice for conduct occurring outside the licensed pharmacy system*.

I would welcome the opportunity to meet with you and your team promptly to discuss a risk-based enforcement approach that targets real bad actors, preserves continuity of care, respects prescriber medical judgment, and remains faithful to the statute Congress enacted.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

The Alliance for Pharmacy Compounding *is the industry trade association and the voice for pharmacy compounding, representing more than 600 compounding small businesses — including 7,500 compounding pharmacists and technicians in both 503A and 503B settings — as well as prescribers, educators, researchers, and suppliers*.
