



THE SHORTAGE IS OVER. THE RISKS ARE NOT:

How Illegal Mass Compounding
Is Undermining Patient Safety—
And What Must Happen Next

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EXECUTIVE SUMMARY

The GLP-1 shortage is over, but the risks associated with mass compounding remain, and they need to be addressed.

Americans are clear about what they value and expect from their GLP-1 medications: U.S. Food and Drug Administration (FDA) approval, expert review, and clinical testing.

Recent survey results revealed a significant difference in expectations and reality:



84% of consumers say FDA approval, expert review, and clinical testing are important when choosing a GLP-1.



9 in 10 current GLP-1 users say those same safeguards are important.



Only 17% of consumers correctly understand that compounded GLP-1s are not FDA approved.



Roughly half of current GLP-1 users mistakenly believe compounded versions have gone through the same approval and testing process as FDA-approved medicines.



82% of general medicine physicians have encountered patients who are unaware that compounded medications are not approved by the FDA.¹

BACKGROUND

During the FDA-declared shortage of medicines such as Ozempic, Wegovy, Mounjaro, and Zepbound, temporary compounding exemptions expanded patient access. As FDA-approved supply has returned, however, some compounders have continued producing and distributing compounded semaglutide and tirzepatide through telehealth platforms, wellness clinics, and other direct-to-consumer channels.

What began as a temporary access pathway has evolved into a parallel market operating outside key FDA safeguards for safety, quality, and transparency. FDA inspections, recalls, warning letters, and state enforcement actions have identified contamination risks, sterility failures, questionable sourcing practices, and misleading marketing tied to compounded GLP-1 products.²

ESCALATING RISKS AND THE PATH FORWARD



UNSAFE COMPOUNDING PRACTICES ARE CREATING PATIENT SAFETY RISKS

Compounded GLP-1 products are not subject to the same standards as FDA-approved medicines, yet many continue to be distributed nationwide at industrial scale. Regulators have documented contamination concerns, sterile-compounding failures, and recalled injectable products. One analysis found adverse events from compounded GLP-1s required hospitalization more than twice as often as those associated with FDA-approved versions.³ Some compounders continue large-scale production through minor formulation changes or claims of “personalization” after the shortage ended.⁴

RECOMMENDED ACTIONS:

- Strengthen enforcement against illegal mass compounding;
- Clarify limits on copycat compounding practices;
- Require adverse event reporting for sterile injectable compounders; and
- Require clear labeling identifying compounded GLP-1s as non-FDA-approved medicines.



ILLICIT SUPPLY CHAIN HAS CREATED A PARALLEL MARKET

Many mass compounders rely on sourcing and production channels that would not satisfy standards applied to FDA-approved manufacturers. Government officials have identified concerns involving foreign ingredient suppliers, unverified import channels, and products containing contaminants or excessive impurities.⁵ The growth of telehealth platforms, med spas, and wellness clinics has expanded distribution of these products directly to consumers, at times contributing to adverse health events.⁶

RECOMMENDED ACTIONS:

- Strengthen oversight of ingredient sourcing and importation;
- Expand inspection authority for high-volume compounders;
- Apply consistent quality standards to industrial-scale operations; and
- Increase accountability for telehealth distributors and medical spas.



MISLEADING MARKETING IS PREVENTING INFORMED CONSUMER CHOICE

Consumers are frequently led to believe compounded GLP-1s are equivalent to FDA-approved medicines despite not undergoing FDA review for safety or effectiveness. FDA warning letters have cited companies for false or misleading marketing claims, while survey data suggest many consumers incorrectly believe compounded GLP-1s are FDA approved or subject to the same testing and oversight standards as branded medicines.^{1,7}

RECOMMENDED ACTIONS:

- Increase enforcement against misleading GLP-1 marketing claims;
- Strengthen oversight of telehealth advertising and distribution practices; and
- Require standardized disclosures distinguishing compounded products from FDA-approved medicines.

RESTORING ACCOUNTABILITY TO THE GLP-1 MARKET

The GLP-1 shortage is over. The mass-compounding market it enabled should be, too.

Industrial-scale production of knockoff GLP-1s demands stronger enforcement, increased supply chain oversight, and one clear standard for patient safety and accountability.

INTRODUCTION

Americans are clear about what they value and expect from their GLP-1 medications: U.S. Food and Drug Administration (FDA) approval, expert review, and clinical testing.

A new survey from Americans for Safe and Effective Medicines (ASEM) found that 84 percent of consumers say each of those safeguards is extremely or very important when choosing a GLP-1 medication. Among current GLP-1 users, that rises to 90 percent.

Yet most patients do not know that not all products available to them meet those standards. In fact, only 17 percent of Americans know compounded GLP-1s are not FDA approved.

Among current GLP-1 users, misunderstanding around regulatory oversight is high. Fifty-one percent mistakenly believe compounded GLP-1 products have been approved by the FDA.¹

Furthermore, providers are seeing the confusion firsthand: 82 percent of general medicine physicians report encountering patients who do not know compounded drugs are not FDA approved.¹

The findings point to a clear disconnect between the safeguards patients say they expect and what they understand about compounded GLP-1 medications.

During the brief GLP-1 shortage, certain compounders were permitted to dispense compounded versions of semaglutide and tirzepatide — the active ingredients in the popular diabetes and weight-loss medications Ozempic, Wegovy, Mounjaro, and Zepbound — to help address temporary supply constraints. Although the shortage has ended, compounded versions of these products continue to be mass marketed and mass dispensed. Many patients do not realize that compounded products are not required to undergo clinical testing, and are not subject to the same manufacturing, labeling, and post-market surveillance requirements as FDA-approved medicines.

The gap between consumer expectations and regulatory reality has become a growing patient-safety concern.

When the GLP-1 drug shortage ended, so did the justification for mass compounding. However, some compounders continue to exploit that temporary access pathway, sustaining a market for unapproved compounding of semaglutide and tirzepatide. The compounded products are linked to dosing errors, adverse events requiring medical attention or hospitalization, and concerns regarding product quality and approved ingredients.⁸ Despite the official end of the drug shortage and escalating FDA enforcement, they continue to move through telehealth



THE EXPECTATION GAP:¹

- **84% of consumers** say FDA approval, expert review, and clinical testing are important when choosing a GLP-1.
- **9 in 10 current GLP-1 users** say those same safeguards are important.
- **Only 17% of consumers** knew that compounded GLP-1 products are not FDA approved.
- **Roughly half of current GLP-1 users** mistakenly believe compounded versions have gone through the same approval and testing process as FDA-approved medicines.
- **82% of general medicine physicians** have encountered patients who are unaware that compounded products are not approved by the FDA.

platforms, medical spas (med spas), and other channels. What was designed as a very limited exception has become a growing health risk. Across the country, mass compounders are continuing to distribute knockoff GLP-1s while avoiding the safeguards required of FDA-approved medicines: clinical review, verified sourcing, batch consistency, standardized labeling, adverse event reporting, and meaningful accountability when patients are harmed.

This paper is not about lawful, patient-specific compounding within the narrow limits of federal law. It is about the rise of industrial-scale mass compounding operating outside the rules designed to protect patients and preserve the integrity of the U.S. pharmaceutical supply chain.

Patients are already bearing the cost.

FDA inspections, recalls, warning letters, state enforcement actions, and patient reports have documented sterility failures, contaminated products, unlawful sourcing practices, misleading marketing, overdoses, emergency care, and hospitalizations.² These are not theoretical regulatory violations. They are preventable patient safety failures associated with a market that continues to expand after its shortage-era rationale expired. Where relevant, this paper distinguishes confirmed regulatory findings from allegations.

This report examines three escalating risks:

- Unsafe compounding practices that create preventable patient harm
- Illicit supply chains that undermine pharmaceutical integrity
- Misleading marketing that conceals critical information from patients

But identifying the risks is not enough. This paper also outlines a solutions-oriented path forward: enforcing the guardrails that already exist, preventing illicit pharmaceutical ingredients from entering the U.S. supply chain, and holding bad actors accountable so patients can access GLP-1 therapies with confidence and protection.

Patients deserve one consistent standard for medicine safety, transparency, and accountability.



THE RISK IN NUMBERS:

- More than **650,000 doses** of compounded drugs have been recalled since 2022, with **75,000** of those doses being GLP-1s.⁹
- Compounded products are linked to a **19x higher likelihood** of contamination reports, with hospitalizations for adverse events **2.35x more likely**.³
- **72%** of actions against active pharmaceutical ingredient (API) manufacturers involved sites that solely supply compounding pharmacies, though those sites represent just **18%** of API manufacturers.¹⁰
- More than **80 to 100 FDA warning letters** have been sent to compounders and telehealth providers for misleading advertising.¹¹
- **57%** of websites fail to disclose that compounded GLP-1s are not FDA approved, while **63%** state only that they have the same active ingredient as the approved drug.¹²



CONFUSION AROUND MASS-COMPOUNDED GLP-1s DECEIVES PATIENTS INTO THINKING:

- Medicines are sterile
- Ingredients are verified
- Products are consistently manufactured
- Safety problems are tracked and reported
- Injectable drugs meet uniform safety standards



MASS-COMPOUNDED PRODUCTS ARE NOT GENERICS. THEY DO NOT:

- Undergo FDA review for safety or effectiveness
- Use standardized labeling
- Require full adverse event reporting to the FDA
- Meet the same manufacturing oversight standards as FDA-approved medicines

UNSAFE AND ILLEGAL MASS COMPOUNDING IS CREATING PREVENTABLE PATIENT HARM

Mass compounders are continuing to distribute GLP-1 products without the safeguards that make medicines trustworthy. FDA-approved therapies must meet standards for safety, effectiveness, manufacturing consistency, labeling, and quality. Compounded GLP-1 products are not held to those same requirements. Patients often have no reliable way to know whether the product they receive is sterile, accurately labeled, correctly dosed, or chemically consistent from one vial to the next.

Those risks become more dangerous at scale. These are not isolated, patient-specific preparations made for narrow clinical circumstances. Many mass compounders are distributing standardized injectable products nationwide through telehealth platforms, med spas, and direct-to-consumer channels while claiming exemptions intended for individualized pharmacy compounding.

The reality is often different.

CASE STUDY: EMPOWER PHARMACY

Empower Pharmacy — which describes itself as “the nation’s premier 503A compounding pharmacy and 503B outsourcing facility” — illuminates the risks that emerge when sterile compounding occurs at industrial scale.¹³ FDA records document sterility and quality control issues at Empower dating back to at least 2015 and continuing through inspections cited in warning letters sent in 2025.^{14,15}

FDA inspectors observed repeated issues including sterile-compounding failures such as:

- Visibly dirty equipment and production surfaces
- Use of ingredients not intended for pharmaceutical use
- Bacterial contamination events during injectable drug manufacturing
- Injectable batches released despite bacterial findings described as “too numerous to count”¹⁶

These were not minor paperwork violations. Empower’s facilities have recalled thousands of compounded products due to a lack of sterility assurances, including more than 8,000 testosterone cypionate vials in 2025.¹⁷ The company has also faced sanctions, probation, or regulatory scrutiny from multiple state pharmacy boards including California, Iowa, and Oklahoma.^{18,19}

California regulatory filings further describe alleged patient-harm incidents involving Empower’s compounded products, including a testosterone preparation allegedly containing approximately ten times the labeled concentration of active ingredient, as well as reports of injection-site injuries, bacterial infections, vomiting, and anaphylaxis after administration of the compounded injectable products.¹⁹

The FDA issued two warning letters to Empower facilities in 2025 following inspections identifying sterile compounding deficiencies.^{15,20} Subsequent reporting on a later FDA inspection indicated that investigators identified additional concerns after those warning letters had already been issued.²¹ This inaction has been accompanied by allegations of fatal patient harm. In April 2026, the family of a Texas woman filed a wrongful-death lawsuit alleging that a compounded GLP-1 product dispensed by Empower was contaminated and defectively formulated, causing injuries that ultimately led to her death.²²

Taken together, the regulatory record reflects recurring sterility, contamination-control, and compliance concerns rather than isolated deficiencies.

Empower is not an outlier. Compounders including ProRx, Thrive Health, and GenoGenix have recalled compounded GLP-1 products or have been cited by the FDA for sterility failures, visible contaminants, and excessive bacterial endotoxins.^{23,24,25}

The patient harm is already visible. Patients have reported overdoses, hospitalizations, septic infections, and acute liver failure following compounded GLP-1 use.²⁶ One analysis found that adverse events from compounded GLP-1s required hospitalization more than twice as often as those associated with FDA-approved versions.³ And because state-licensed pharmacies that are not outsourcing facilities are generally not required to report adverse events to FDA, the public record understates the true scale of harm.⁸

These failures point to a clear enforcement gap: mass compounders are operating at a scale and risk level that the current framework was never designed to tolerate. Protecting patients requires moving beyond warnings and ensuring that any entity distributing sterile injectable products is held to meaningful safety, quality, and reporting standards.

The Personalization Scam

Congress established strict limits on compounding to ensure it remained a narrow, patient-specific practice for individuals with demonstrated medical need — not a vehicle for ongoing industrial-scale manufacturing of knockoff drugs.

After the GLP-1 shortage ended, some compounders complied and stopped. But others adopted what can only be described as scam “personalization” schemes — manipulating products in pretextual ways, by adding vitamins or adjusting dosages, to preserve large-scale production while continuing to claim the legal protections intended for individualized compounding.⁸

One investigation found it was “remarkably easy” to obtain compounded GLP-1s without meaningful individualized review, lab work, or medical documentation.²⁷

These practices bear little resemblance to the narrow patient-specific compounding Congress intended to protect.

We encourage lawmakers and regulators to:

- Strengthen FDA enforcement against illegal mass compounding outside federal compounding law
- Require adverse event reporting for compounders that distribute sterile injectables
- Strengthen sterility, potency, and batch-consistency standards for compounded injectables
- Clarify the “essentially a copy” standard so compounders cannot evade limits by making minor changes to FDA-approved medicines, such as adding ingredients, adjusting doses, or claiming routine personalization
- Require standardized labeling and patient disclosures explicitly delineating compounded GLP-1s as non-FDA-approved medicines

SOME MASS COMPOUNDERS ARE OPERATING THROUGH ILLICIT SUPPLY CHAINS, CREATING A PARALLEL PHARMACEUTICAL MARKET

FDA-approved medicines are subject to strict sourcing, inspection, manufacturing, and reporting standards to ensure products are safe, consistent, and traceable throughout the supply chain. Many mass compounders operating in the GLP-1 market continue to rely on sourcing and distribution channels that would not satisfy the standards applied to FDA-approved manufacturers.

As compounded GLP-1 distribution expanded, many operators increasingly relied on foreign API suppliers, unverified import channels, and industrial-scale production models that federal compounding exemptions were never intended to support. The FDA has warned that foreign-made GLP-1 bulk drug substances may be manufactured without adequate controls to assure quality, and established Import Alert 66-80 to detain GLP-1 bulk drug substances with potential quality concerns.²⁸ While the alert is helpful, it is imperfect and does not address retroactive issues.



FOREIGN API RISKS BY THE NUMBERS

- More than one-fifth of 48 GLP-1 API manufacturing sites assessed by FDA were non-compliant or failed to provide required records.²⁸
- Among Chinese firms responsible for the roughly 20% of semaglutide imported into the U.S. for compounding, several had never been inspected by FDA, while others were cited for inspection violations.²⁹
- An analysis of GLP-1 API shipments identified 239 problematic shipments tied to unregistered entities with no FDA-listed semaglutide or tirzepatide products.³⁰

CASE STUDY: UNSAFE INGREDIENT SOURCING

FDA issued a warning letter to Darmerica after investigators identified compounded drug ingredients sourced from foreign facilities with significant regulatory compliance concerns. Regulators also cited failures involving supplier verification and practices that obscured ingredient origins.³¹

FDA found that the Chinese company Harbin Jixianglong Biotech had shipped relabeled semaglutide API sourced from non-approved suppliers and released tirzepatide API without validated analytical methods, adequate stability studies, or appropriate endotoxin/microbial testing.³²

Why This Matters

Patients reasonably assume injectable medicines are made from verified pharmaceutical ingredients sourced through accountable supply chains. Cases like Darmerica and Harbin Jixianglong Biotech illustrate how gaps in oversight can allow questionable or inadequately verified ingredients to enter compounded products distributed to American patients.

The result is a dangerous double standard. FDA-approved manufacturers must verify sourcing, validate production, test consistency, report adverse events, and comply with inspection and recall obligations. Mass compounders distributing similar injectable products nationwide often avoid those same requirements by continuing to claim exemptions designed for one-off, patient-specific pharmacy compounding.

Testing and enforcement records from the Federal Bureau of Investigation show why that gap matters. In a public service announcement, the agency reported that some compounded products contained no semaglutide at all, while others contained unidentified contaminants or excessive impurity levels. The same announcement described a case in which a med spa allegedly sold an injectable mixture of animal-grade semaglutide and Vitamin B12 — a product that should never have entered the human pharmaceutical supply chain.⁵

A PARALLEL MARKET OUTSIDE THE RULES

The integrity of the U.S. pharmaceutical supply chain cannot coexist with a parallel system sourcing ingredients from uninspected facilities, distributing injectable drugs nationwide, and operating without the quality and accountability standards required of FDA-approved medicines.

The problem extends beyond pharmacies. Med spas and wellness clinics have become major distribution channels for compounded injectable products. Ohio regulators shut down more than 30 med spas following findings involving unsanitary preparation practices and failures to ensure sterile conditions.³³ New York regulators similarly identified widespread sanitation and hygiene failures, along with reports of counterfeit injectable products causing allergic reactions, poisoning, and other injuries.⁶

When unverified ingredients, questionable import channels, and high-volume distribution converge, the result is an unregulated pharmaceutical market that patients cannot evaluate, and regulators cannot allow to persist. Closing that market requires stronger oversight at every point where these products enter, move through, and reach the U.S. healthcare system.

We encourage lawmakers and regulators to:

- Strengthen FDA and U.S. Customs and Border Protection (CBP) coordination to target unlawful API importation
- Require transparency around ingredient sourcing and supplier verification
- Expand inspection and manufacturing oversight for high-volume compounders
- Apply consistent quality standards to compounders operating at industrial scale
- Increase accountability for med spas, telehealth distributors, and interstate dispensing channels

MISLEADING MARKETING IS KEEPING PATIENTS IN THE DARK

Some mass compounders have built their market by obfuscating the line between FDA-approved medicines and untested compounded products. Across telehealth platforms, online ads, and direct-to-consumer marketing campaigns, patients are routinely led to believe compounded GLP-1s are equivalent to approved therapies — even though these products have never undergone FDA review for safety, effectiveness, or manufacturing consistency.

This confusion is reinforced by marketing practices that the FDA has already challenged. Many compounders use clinical trial results generated for FDA-approved medicines while marketing their own products as “personalized,” “tailored,” or “equivalent” alternatives. That language creates the appearance of scientific validation without the testing, oversight, or accountability that gives FDA-approved medicines their credibility.^{4,11}

CASE STUDY: FDA CRACKDOWN ON TELEHEALTH GLP-1 MARKETING

In 2026, the FDA issued warning letters to 30 telehealth companies for illegally marketing compounded GLP-1 products with false or misleading claims, after over 50 letters were sent out in 2025.^{7,34} Regulators cited companies for suggesting compounded products were equivalent to FDA-approved medicines such as Wegovy and Ozempic, despite compounded GLP-1s not being FDA approved and not being required to undergo clinical testing or demonstrate bioequivalence.²

The FDA also warned that some companies marketed compounded GLP-1s in ways that obscured the regulatory status of the drugs being sold, contributing to consumer confusion about whether compounded products had been reviewed or approved by the FDA.⁷

Federal regulators have already identified these practices as unlawful. The FDA has issued warning letters targeting false or misleading marketing of compounded GLP-1 products, including claims that blur the line between compounded drugs and FDA-approved medicines.⁷

The public misunderstanding is significant. Survey data shows that many consumers incorrectly believe compounded GLP-1s are FDA approved.¹ Patients seeking treatment are often not told that compounded products are exempt from clinical testing, bioequivalence standards, standardized labeling, and post-market surveillance requirements.

The marketing is not incidental to the harm — it is the mechanism that permits it.

Unlike FDA-approved therapies, compounded products are not required to provide standardized prescribing information, validated dosing instructions, contraindication disclosures, or consistent risk warnings. Patients may receive products with materially different formulations, concentrations, or inactive ingredients without understanding how those differences could affect safety or efficacy.

Misleading marketing allows this shadow market to continue reaching patients. If consumers are led to believe compounded products are FDA approved, clinically proven, or equivalent to branded therapies, they cannot make informed decisions about their care.

We encourage lawmakers and regulators to:

- Target false or misleading GLP-1 compounding claims through FDA and Federal Trade Commission enforcement
- Strengthen oversight of telehealth distribution platforms
- Require standardized patient risk disclosures and labeling that distinguish compounded products from FDA-approved medicines
- Enforce against unlawful claims of equivalence, personalization, or FDA approval

WHEN EXPECTATIONS AND REALITY DIVERGE

Consumers and physicians overwhelmingly agree that FDA approval, independent review, and clinical testing matter. Yet the record documented throughout this report shows that many compounded GLP-1 products are marketed and distributed without those safeguards.

The problem is not simply that consumers lack information. The problem is that patients are making decisions in a market where marketing often obscures the distinction between FDA-approved medicines and compounded alternatives. Survey findings show that many current GLP-1 users mistakenly believe compounded products have undergone the same review and testing as FDA-approved therapies, while physicians report encountering that confusion routinely in clinical practice.¹

That misunderstanding carries consequences as GLP-1 users are more likely to be misinformed than non-users.¹ Patients who believe a product has been clinically tested and reviewed by FDA may reasonably assume it meets the same standards for manufacturing quality, sourcing, labeling, dosing consistency, and safety monitoring. As this report demonstrates, those assumptions are not always warranted.

Closing the gap will require more than public education. It will require stronger enforcement, clearer disclosures, greater transparency, and accountability for entities that market compounded products in ways that blur the line between approved medicines and unapproved alternatives.

RESTORING ACCOUNTABILITY TO THE GLP-1 MARKET

GLP-1 therapies are among the most important pharmaceutical advances in recent years, with the capacity to support millions of patients who need them. Their promise should not be undermined by a parallel market that continues to grow after the shortage rationale has ended.

The record is clear: contamination, sterility failures, unlawful sourcing, misleading marketing, product recalls, and patient harm are not isolated events. They are symptoms of a market operating outside the safeguards designed to protect patients.

Patients should be able to access GLP-1 therapies with confidence that the products they receive are safe, verified, and subject to meaningful oversight.

The path forward does not require reinvention of the regulatory system. It requires enforcement of the one we already have, holding bad actors accountable, and restoring the principle that medicines sold to American patients should meet clear, consistent, and verifiable standards.

The shortage is over. Now the mass-compounding market must end, too.

The path forward is achievable. Regulators and policymakers can protect patients by:

- Enforcing existing limits on mass compounding
- Closing supply chain gaps
- Requiring clear disclosures
- Holding bad actors accountable when they mislead consumers or distribute unsafe products

A POLICY AND REGULATORY ROADMAP TO PROTECT PATIENTS FROM ILLEGAL MASS COMPOUNDING

Protecting patients from illegal mass compounding requires coordinated action across federal and state regulators, enforcement agencies, and policymakers. The following recommendations outline practical steps to strengthen oversight, improve transparency, and reduce preventable patient harm.

FOCUS AREA	RECOMMENDATION
COMBATTING PREVENTABLE PATIENT HARM	
Enforcement	Strengthen FDA enforcement against illegal mass compounding outside federal compounding law
Safety Reporting	Require adverse event reporting for compounders that distribute sterile injectable products
Product Quality	Strengthen sterility, potency, and batch-consistency standards for compounded injectables
Regulatory Clarity	Clarify the “essentially a copy” standard so compounders cannot evade limits through minor formulation changes
Patient Transparency	Require standardized labeling and patient disclosures identifying compounded GLP-1s as non-FDA-approved medicines
UPHOLDING SUPPLY CHAIN STANDARDS	
Import Controls	Strengthen CBP coordination to target unlawful API importation
Supply Chain Transparency	Require transparency around ingredient sourcing and supplier verification
Manufacturing Oversight	Expand inspection and manufacturing oversight for high-volume compounders
Quality Standards	Apply consistent quality standards to compounders operating at industrial scale
Distribution Accountability	Increase accountability for med spas, telehealth distributors, and interstate dispensing channels
CRACKING DOWN ON FALSE AND MISLEADING ADVERTISING	
Marketing	Target false or misleading GLP-1 compounding claims through FDA and FTC enforcement
Platform Oversight	Strengthen oversight of telehealth distribution platforms
Consumer Disclosures	Require standardized patient risk disclosures and labeling that distinguish compounded products from FDA-approved medicines
Truth-in-Advertising	Enforce against unlawful claims of equivalence, personalization, or FDA approval

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