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FDA Takes Aim at Drug Ads: What It Means for Compounding Pharmacies, Medspas and Telehealth Companies

Key Takeaways

- **FDA has launched an aggressive new crackdown on direct-to-consumer (DTC) drug advertising**, issuing nearly 100 cease-and-desist letters and thousands of notices — many targeting compounding pharmacies, medspas and digital health platforms.
- **Telehealth companies and online platforms are now firmly in FDA's sights**, despite historically operating outside the agency's enforcement scope. This marks a major shift in how FDA is asserting jurisdiction over advertising conducted by intermediaries.
- **Even technical or low-level violations may now trigger scrutiny**, as FDA deploys AI surveillance tools and flags issues like "attention-grabbing visuals" and implied off-label uses.
- **Companies should act now** and audit all drug-related advertising for implied approval claims, review risk tolerance and be prepared for follow-up enforcement.

Earlier this month, the U.S. Food and Drug Administration (FDA) launched its most sweeping direct-to-consumer (DTC) advertising crackdown in years.

As part of the Trump Administration's effort to address misleading DTC prescription drug advertisements, FDA sent thousands of notices and nearly 100 cease-and-desist letters to companies it says are running misleading drug ads. While some went to several major pharmaceutical companies like Novartis, Novo Nordisk and Eli Lilly, the vast majority were directed at compounding pharmacies, medical spas and telehealth platforms — including well-known companies like Hims & Hers — for their purportedly misleading claims about compounded GLP-1 products. [1]

This wave of compliance activity is unprecedented, not just in volume, but also in focus. While FDA had previously issued more than one hundred warning letters annually for misleading drug advertisements, that number has recently dwindled to only a few each year. Now, the agency is signaling a sharp reversal. For the first time, it has swept in online telehealth platforms that are arguably outside FDA's jurisdiction — indicating a willingness to test the limits of its authority in the digital health space.

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FDA Ramps Up Enforcement with AI-Powered Surveillance

In its public statements, FDA indicated it plans to return to 1990s-era enforcement levels, despite considerable staff reductions earlier this year, particularly its Office of Prescription Drug Promotion.

According to FDA, newly adopted AI tools will play a key role in identifying violations, enabling the agency to efficiently — and aggressively — monitor the marketplace.

The shift to AI tools is already evident, as many of the warning letters relied on standard, template language, and the agency noted it will flag more "technical" violations in prescription drug advertising — like "attention grabbing visuals" or "frequent scene changes" — that historically wouldn't trigger FDA action, absent more flagrant deceptive advertising practices.

For example, in a separate untitled letter to AstraZeneca, FDA noted that a commercial showing teenagers discussing drug use without a caregiver implied that the product could be self-administered by individuals aged 2 to 17 — a use not supported by the drug's label. Companies should be aware that even minor violations could draw FDA scrutiny.

Digital Health Platforms Test the Boundaries of FDA Oversight

Until now, digital health platforms — including those flagged in this enforcement sweep[2] — have operated in a regulatory gray zone.

FDA's enforcement authority under the Federal Food, Drug, and Cosmetic Act (FDCA), is typically limited to several "prohibited acts" related to developing, manufacturing, distributing, selling, marketing, holding for sale and labeling regulated products,[3] like introducing an adulterated or misbranded regulated product or unapproved new drug into interstate commerce.[4] FDA-approved prescription drugs also have restrictions on DTC advertising, including that all ads contain a fair balance between information related to side effects and contraindications and information related to the effectiveness of the drug.[5]

However, most telehealth platforms *don't* engage in these traditionally FDA-regulated activities.[6] Instead, they connect consumers to independent licensed telehealth providers, who prescribe compounded GLP-1s that are then filled at independent compounded pharmacies, usually at a steep discount to FDA-approved versions. And as we noted in a prior alert, compounded drugs are exempt from most FDA regulations on direct-to-consumer advertising. Even so, FDA included telehealth platforms in its latest enforcement push.

Enforcement Push Reaches Telehealth Platforms

A few days after the sweep, FDA Commissioner Martin Makary specifically criticized Hims & Hers's Super Bowl ad as a "brazen" violation of FDA's fair and balanced regulations.[7] But the warning letter issued to Hims & Hers and similar companies told a narrower story. It didn't cite the Super Bowl ad or raise fair-balance concerns. Instead, it only alleged violations FDA's misbranding provisions for claims that implied the compounded products were FDA-approved, when they are not[8] — for example, that they contain the "same active ingredient as Ozempic and Wegovy" and that the ingredients are "clinically proven."

Compounded Drugs, Unclear Rules and a Compliance Catch-22

This disconnect exposes a deeper regulatory tension. Unlike their FDA-approved counterparts, compounded drugs, by definition, are not FDA-approved. They therefore lack an FDA-approved label — meaning they have no official indications and are not

required to provide adequate directions for use, contraindications and side effects.

This places compounded pharmacies in a difficult position. On one hand, they are prohibited from implying that their products are equivalent to FDA-approved medications. On the other, they're now being criticized for omitting information that only exists in FDA-approved labeling. That regulatory catch-22 makes it especially challenging for platforms to navigate promotional claims without drawing scrutiny.

FDA's Authority Remains Unclear — and Unchallenged

FDA hasn't formally explained how it views its jurisdiction over digital health platforms, but its recent actions suggest a potential theory: it could be taking the position that digital health platforms, telehealth services and compounding pharmacies are acting as a "common enterprise" by causing prohibited acts under the FDCA, bringing them within FDA's authority.

Yet the warning letters offer little clarity. They follow a standard, copy -and -paste template, citing to general misbranding provisions of the FDCA and listing problematic promotional claims — without the detailed legal analysis typically found in traditional FDA warning letters. Historically, FDA warning letters have included more background information and detailed explanations for why the alleged advertisements did not comply with specific provisions of the FDCA and implementing regulations.

That departure from the norm creates a conundrum for the industry. Because warning letters are not final agency actions, they typically can't be challenged in court. Companies are therefore left to interpret FDA's vague position without a clear mechanism to dispute it until FDA takes a final enforcement action, like implementing criminal or civil penalties. Until then, FDA's assertion of its expanded regulatory authority is likely to go untested.

What Companies Can Do Now

Addressing the violations in the warning letters is relatively straightforward exercise for most digital health platforms. But as FDA enters a new era of aggressive enforcement, it is crucial for companies operating in the digital health and compounding space to reassess their practices.

Below are three key areas companies should focus on now to reduce risk and prepare for what's next:

1. **Anticipate additional enforcement.** This initial round of "warning letters" is likely just the start. Companies choosing to ignore FDA's letters could find themselves facing additional adverse publicity and harsher FDA enforcement efforts such as civil or criminal penalties, including fines, seizures, or disbarment. FDA stated that it intends to "aggressively" deploy its available enforcement tools moving forward, suggesting the Agency will continue to pay close attention to prescription drug advertising and social media promotion. The initial flurry of letters and press releases was intended to gain the attention of the industry; further FDA action is likely to focus on companies who FDA thinks failed to get the message. Companies not included in this first round should not assume they are exempt from scrutiny and should reassess their risk tolerance as the FDA intensifies its enforcement efforts.
2. **Audit advertising practices.**With FDA's new focus on digital health platforms, companies should audit their advertising practices and carefully review any claims suggesting that compounded drug products are equivalent to FDA-approved counterparts. For instance, statements that a compounded product contains the same active ingredients as a brand-name drug, is clinically proven, or is as effective as an FDA-approved product, are likely to attract FDA attention, including a warning letter or

untitled letter.

3. **Pay attention to the details.** With FDA using AI tools for surveillance, even minor or technical missteps can now trigger enforcement. Recent letters have flagged things like fast scene changes or implied age ranges — details that might previously have flown under the radar. Companies should assume that every visual, phrase and impression is on the table for review.

Polsinelli's FDA group regularly advises telehealth providers, pharmacies and drug manufacturers on a wide range of compliance issues, including advertising, regulatory submissions and pre- and post-marketing requirements. To discuss how this evolving enforcement environment may affect your business, please contact the authors or a member of our FDA Regulatory practice.

1 *See e.g.*, Food & Drug Admin., Warning Letter to Cosmo Medical Spa (Sept. 9, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cosmo-medical-spa-dba-cosmo-med-spa-09092025.

2 Food & Drug Admin., Letter to Pharmaceutical Companies, (Sept. 9, 2025), https://www.fda.gov/media/188616/download?attachment.

3 21 U.S.C. § 331.

4 21 U.S.C. § 331 (a)-(d).

5 21 C.F.R. § 202.1.

6 21 U.S.C. § 352(n)

7 Martin A. Makaray, *The FDA's Overdue Crackdown on Misleading Pharmaceutical Advertisements*, JAMA (Sept 12, 2025), https://jamanetwork.com/journals/jama/fullarticle/2839061.

8 Food & Drug Admin., Warning Letter to Hims & Hers, (Sept. 9, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hims-hers-health-inc-dba-hims-09092025.