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National Advertising Division Puts Compounded GLP-1 Advertising on a Diet

Key Takeaways

- A recent NAD decision underscores that advertising compounded drugs in a way that implies they share the benefits of FDA-approved medications will likely be deemed deceptive by regulators.
- The FDA significantly increased its compliance activity surrounding advertising for compounded drugs in 2025, and recent remarks from an FDA official highlighted the agency's concerns about claims that state or imply the equivalence of compounded drugs to approved drugs.
- As we've written previously, companies promoting or manufacturing compounded GLP-1 drugs should thoroughly audit their advertising practices in light of the recent enforcement activity.

On Dec. 4, 2025, the National Advertising Division (NAD), which reviews advertising challenges, released an opinion recommending that Willow Health Services, Inc., a Texas-based telehealth company, modify or discontinue several health claims for its compounded semaglutide tablets.[1] This comes as Novo Nordisk and Eli Lilly continue to aggressively challenge compounded versions of their GLP-1 medications. A U.S. Food and Drug Administration (FDA) senior compliance official also recently reiterated the agency's concern regarding certain advertising claims in this space.

As we noted in a recent update and earlier this year, telehealth companies, compounding pharmacies, medspas and other businesses promoting, manufacturing or facilitating access to compounded GLP-1 drugs should audit their advertising practices to take into account recent challenges and FDA activity.

Advertisers Face Growing NAD Challenges Over Compounded GLP-1 Claims

The NAD is part of the Better Business Bureau and an independent system of self-regulation that reviews advertising for truth and accuracy. Its review standards closely align with the Federal Trade Commission (FTC) Act and FTC guidelines. NAD reviews advertising challenges initiated by consumers, businesses, trade associations or on its

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- Food, Drug & Device
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own accord. Participation in the NAD process is voluntary, and NAD holds no mechanism to enforce its recommendations. However, if an advertiser subject to a challenge refuses to participate in the process or follow NAD's recommendations, NAD will refer the matter to the appropriate regulatory agency, including the FTC, FDA and state attorneys general. NAD findings of deceptive advertising may also serve as blueprints for plaintiffs' lawyers pursuing claims under state consumer protection laws.

This year, both Eli Lilly and Novo Nordisk have filed several NAD challenges against compounding pharmacies, telehealth companies and medspas marketing compounded versions of semaglutide and tirzepatide.[2] These challenges alleged that the advertisers' claims regarding the health benefits, safety and effectiveness of the compounded products were false, misleading and/or unsubstantiated.

In prior challenges, advertisers chose to voluntarily discontinue the disputed claims rather than engage in the NAD process. When a claim is voluntarily discontinued, NAD does not evaluate its merits. However, Willow opted to defend its advertising claims against a challenge from Novo Nordisk, prompting NAD review of their substantiation and truthfulness.

Prescriber Involvement Alone Doesn't Justify Health Claims, NAD Says

Willow's primary defense of its claims was that prescribing decisions made by individual doctors who consulted with each Willow customer were sufficient to substantiate that the products were effective weight loss treatments. Willow also pointed to disclosures on its website stating that its semaglutide products have not been subject to clinical trials assessing their safety or effectiveness.

NAD determined that the evidence provided by Willow was insufficient to support its advertising claims. Specifically, NAD rejected Willow's argument based on physician prescribing practices, stating that an expert's "conclusory statement or action is of little value" and that expert opinions are most reliable when coupled with "competent and reliable evidence demonstrating scientific consensus on an issue." NAD also found that studies referenced by Willow concerning the effectiveness of its products for weight loss only involved FDA-approved GLP-1 products and were "insufficient to validate claims for compounded alternatives that differ in active pharmaceutical ingredient, formulation or method of administration." Therefore, NAD concluded that Willow did not establish a reasonable basis for its claims and recommended that Willow discontinue or modify its advertising. Willow did not respond or issue an "Advertiser's Statement" regarding NAD's decision, which led NAD to refer the matter to the appropriate regulatory authorities, including state Attorneys General.

FDA's 2025 Increase in Warning Letters on Compounded Drug Advertising

In recent remarks at the Food and Drug Law Institute's Enforcement, Litigation, and Compliance Conference, the director of the Office of Compliance within FDA's Center for Drug Evaluation and Research's (CDER) noted that 22% of warning letters that CDER issued in fiscal year (FY) 2025 were sent to telehealth platforms and other entities related to claims made regarding compounded drug products, including compounded GLP-1s. These letters contributed to the significant uptick — an increase of 50% overall — in the number of CDER warning letters issued in FY 2025. This increase appears to be largely tied to the U.S. Department of Health and Human Services (HHS) and FDA "crackdown" on direct-to-consumer (DTC) drug advertising.

CDER's compliance director emphasized that compounded drugs are not equal to

approved drugs and that the FDA is concerned about claims suggesting otherwise. She also described FDA's efforts related to advertising around compounded GLP-1s as part of a coordinated approach in FY 2025 that included:

1. Launching a worldwide "green list" import alert announced in September 2025 to help identify and stop import of GLP-1 active pharmaceutical ingredients from unverified foreign sources;
2. Seizing counterfeit GLP-1 products; and
3. Issuing warning letters related to unsafe products, such as those labeled for "research use only" but sold directly to consumers.

While these remarks largely summarize actions FDA has already taken, they highlight compounded GLP-1 products as an area of concern, and this area is likely to be one of continued FDA interest in 2026.

Looking Ahead

GLP-1 drugs have revolutionized treatment for obesity, but recent regulatory activity is a reminder that existing rules apply — even when the innovation is revolutionary.

[1] *Willow Health Services Inc. (Compounded Semaglutide Products),* Report #7488, NAD/CARU Case Reports (November 2025); Better Business Bureau, National Advertising Division Will Refer Willow Health to State and Federal Regulatory Authorities for its Compounded Semaglutide Product Claims, (December 4, 2025) https://bbbprograms.org/media/newsroom/decisions/willow-health.

[2] *See e.g. Regen Doctors (Compounded Semaglutide: Injection, Melts and Drops),* Report #7516, NAD/CARU Case Reports (November 2025); *Fletcher Family Medical Center (Subsema, Compounded Sublingual Semaglutide Product)*, Report #7518, NAD/CARU Case Reports (November 2025*); Striker Pharmacy, LLC (Compounded Tirzepatide + B12 Weight Loss Treatment)*, Report #7446, NAD/CARU Case Reports (May 2025); *Begin Anew MedSpa (Compounded Tirzepatide + B12 Weight Loss Treatment)*, Report #7404, NAD/CARU Case Reports (May 2025); *Hormone Fitness (Compounded Tirzepatide + B12 Weight Loss Treatment)*, Report #7447, NAD/CARU Case Reports (May 2025).