The Partnership for SAFEMEDICINES.org®

WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

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Attn: Standards and Practices

February 5, 2025

We write to you to request that you withdraw the deeply troubling advertisement for unapproved, knock-off weight loss drugs that Hims and Hers Health, Inc. is scheduled to run during the Super Bowl. A variety of commentators have called the ad "incredibly irresponsible."[1] **It is a prescription drug advertisement**, and as such, we believe that is non-compliant with both Fox Broadcasting Company's (FBC) Advertising Guidelines and the FDA and FTC regulations governing commercial advertisements.

Despite clearly being an advertisement for "weight loss medicines," the Hims' spot does not follow "FDA guidelines for prescription drug commercials." In fact, it does not even attempt to. A company spokesman for Hims confirmed that it believes (incorrectly) that it is "exempt from including long read-outs of risks and side effects typically shown in pharma TV commercials" and therefore made no effort to comply with FDA guidelines.[2] Even if Hims' assertion were correct, Hims would then be required to comply with the FTC Act's requirements. The Hims' ad falls well below that standard as well and should be withdrawn under either the FDA or FTC standards.

The compounded product only exists as a knock-off copy of a prescription medication. There is no universe in which Hims and Hers could market their compounded product without the FDA-approved prescription product being approved first. Therefore the advertising guidelines that apply to a prescription medication should apply to the Hims and Hers Super Bowl spot also.

We request that you withdraw this advertisement from your Super Bowl ad plans.

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1 https://www.statnews.com/2025/01/28/super-bowl-ad-hims-and-hers-telehealth-company-downplays-risks-compounded-drugs/.

2 https://www.wsj.com/articles/hims-hers-to-advertise-weight-loss-shots-at-the-super-bowl-e0e92ce1

It does not sufficiently disclose that compounded medications are not FDA-approved.

Hims sells compounded versions of semaglutide, a prescription drug, under the brands "Hims" and "Hers." The FDA has only approved semaglutide sold by Novo Nordisk, under the brands Ozempic, Wegovy, and Rybelsus. Hims claims that it can sell unapproved versions of semaglutide because its drugs are "compounded" by "outsourcing facilities" and not "manufactured" by "drug companies." Federal law constrains the making of compounded products to very narrow circumstances, intended to be a limited exception from the general rule that pharmaceutical products must meet rigorous standards of demonstrated safety and efficacy before they can be approved by FDA and prescribed to patients. But even if a compounded product is made under these exceptions, FDA has expressly cautioned that "compounded drugs are not FDA approved" and are "risky for patients" because they "do not undergo FDA's review for safety, effectiveness and quality before they are marketed."[3] Excluding that information from the ad misleads consumers and puts their health and safety at risk.

It does not disclose risks or side effects necessary for patient protection.

The 60-second commercial, which is publicly available on YouTube,[4] is not simply for "Hims" as a company or a general introduction to its business; it is specifically intended to market Hims' compounded, unapproved semaglutide drugs to consumers. The advertisement shows several images of unlabeled medication vials with the Hims or Hers logos and displays a person using the Hims mobile app. The commercial describes Hims' "life-changing weight loss medications" as "affordable," "doctor trusted," and "formulated in the USA"—though its use of the oblique term "formulated," rather than "manufactured" or "made," raises questions about where its active pharmaceutical ingredient, semaglutide, is sourced, particularly because Novo Nordisk has made clear it does not sell its API to anyone else and there is evidence compounders have been sourcing API from uninspected or unregistered foreign facilities.[5] Despite presenting its product as an alternative to other "medications that work" to treat obesity, the advertisement obscures the fact that Hims' "weight loss medications" are unapproved, compounded products that have not been subject to clinical testing or FDA scrutiny and "pose a higher risk to patients than FDA-approved drugs."[6] Most alarmingly, the commercial makes no mention of side-effects, warnings, or the potentially serious risks posed by any semaglutide product. For instance, the commercial does not disclose that FDA requires a "black box" warning for semaglutide (FDA's strongest type of

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3 FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

4 https://www.youtube.com/watch?v=l5l6QMNnqoc.

5 Newsweek, *Government Needs to Do More to Ensure Obesity Drug Safety*, Grogan, available at https://www.newsweek.com/government-needs-do-more-ensure-obesity-drug-safety-opinion-2000072

6 FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.

warning) about the risk of thyroid cancer. Experts in the field are "shocked" by the ad, noting how the ad "downplays the risks of compounded drugs" and describing it is as "incredibly irresponsible."[7]

It violates several FBC advertising guidelines for drug ads.

The advertisement violates at least two sections of your FBC Advertising Guidelines. First, the Hims' advertisement violates your Guidelines for "Health Related Product Advertising." According to the Guidelines, "[p]rescription drug advertising" must "adequately reflect FDA guidelines for prescription drug commercials." Advertisements must also be "accurate and not misleading," contain all "material facts," communicate "clearly" that the product is "available by prescription only," and instruct viewers to "consult their physicians regarding the product." They must also "disclose the most significant risks that appear in the labeling" and "contain a brief summary of all necessary information related to side effects and contraindications." Hims' advertisement does not comply with any of these requirements, despite being specifically intended to market Hims' prescription drug products including compounded, unapproved semaglutide.

- Despite clearly being an advertisement for "weight loss medicines," the Hims' spot does not follow "FDA guidelines for prescription drug commercials." In fact, it does not even attempt to. A company spokesman for Hims confirmed that it believes (incorrectly) that it is "exempt from including long read-outs of risks and side effects typically shown in pharma TV commercials" and therefore made no effort to comply with FDA guidelines.[8]

- The Hims' advertisement omits the material facts that its "weight loss medications" are compounded and therefore are not FDA-tested or FDA-approved. The only references to compounded products appear in the smallest, lightest colored font used in the ad as fleeting disclosures on the bottom of the screen for roughly 6 seconds, where it could potentially be blocked by closed captions or different TV screen ratios. As researchers who have studied compound pharmacy marketing have already remarked about the commercial, "small text for a few seconds of the ad" does not educate viewers about the risks of compounded products at all.[9] Moreover, disclosing only that the drugs are "compounded" and not reviewed for "safety, effectiveness, or quality" (for approximately three seconds) fails to disclose that FDA has affirmatively *warned* consumers that the products are "risky."[10]

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7 https://www.statnews.com/2025/01/28/super-bowl-ad-hims-and-hers-telehealth-company-downplays-risks-compounded-drugs/

8 https://www.wsj.com/articles/hims-hers-to-advertise-weight-loss-shots-at-the-super-bowl-e0e92ce1

9 https://www.statnews.com/2025/01/28/super-bowl-ad-hims-and-hers-telehealth-company-downplays-risks-compounded-drugs/

10 Other organizations have expressed similar concern. The American Diabetes Association "recommend[ed] against using non-Food & Drug Administration (FDA)-approved compounded GLP-1 and dual GIP/GLP-1 RA products due to uncertainty about their content, safety, quality, and effectiveness."

- The Hims' advertisement does not "communicate clearly to the viewer" that the product is "available by prescription only." There is a brief disclaimer at the bottom of the screen that reads "Prescription required," but it is displayed in miniature font for three seconds and does not "communicate clearly" to the viewer.

- The Hims' advertisement does not advise viewers anywhere to "consult their physician regarding the product."

- The Hims' advertisement makes no mention of "side effects and contraindications." Nor does it list any "significant risks" for the product. Indeed, unlike FDA-compliant advertising, the Hims' advertisement makes no effort to strike a fair balance between benefit and risk information, a point confirmed by independent experts.[11] Such a one-sided presentation of a purportedly "life-changing" product—one without any clinical safety testing—also renders the ad "misleading," in violation of your Guideline on Substantiation, and constitutes an "Unacceptable Commercial Approach[], Presentation[], or Technique[]" by making "unqualified references to the safety of a product, if package, label or insert contains a caution, or the normal use of the product presents a possible hazard," given that even FDA-approved semaglutide requires FDA's strongest "black box" warning for use.

Even accepting Hims and Hers claim that they are not promoting a prescription weight loss drug, the ad would still fail the FBC Ad Guidelines standard for weight loss/control products because it does not substantiate its claims.

Second, the Hims' advertisement violates your specific Guidelines for "weight loss/control products." Those Guidelines require all "[c]laims for weight loss products or programs" to be substantiated and to be "advertised in the context of an overall healthy program that includes an exercise regimen, a reduction in caloric intake and proper nutrition." Hims' advertisement falls well short of this requirement too. For instance, Hims' unsubstantiated claim that it sells "life-changing weight loss medications" is an "[e]xpress or implied overstatement[] of a product or program's results." Hims has no data or evidence to establish that the compounded products it dispenses to patients are "life-changing" or that they lead to *any* level of weight loss because they have not undergone any clinical testing to substantiate those claims. It therefore also violates your overall Guideline on Substantiation, which requires advertisers to have a "reasonable basis" for claims and to "present objective evidence as support."

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https://diabetes.org/newsroom/press-releases/american-diabetes-association-announces-statement-compounded-incretin#:~:text=The%20statement%20recommends%20against%20using,safety%2C%20quality%2C%20and%20effectiveness. Likewise, the Obesity Society, Obesity Action Coalition, and Obesity Medicine issued a joint statement cautioning that "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be." https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/

[11] https://www.statnews.com/2025/01/28/super-bowl-ad-hims-and-hers-telehealth-company-downplays-risks-compounded-drugs/

The Hims and Hers drug ad must be withdrawn to protect public safety.

We are bringing this serious and urgent public health issue to your attention because of the potential for harm from compounded products, particularly those being marketed today for weight loss. In addition to FDA's general warning that compounded products are "risky" for patients, there are numerous recent examples of specific threats to public health from pharmacy compounding.[12] For example, FDA recently warned patients and health care professionals not to use unapproved GLP-1 injections prepared by a firm in California that had been using "non-sterile ingredients" and "took no steps to sterilize them."[13] Similarly, FDA inspected a Texas compounder and found that it "routinely use[d] non-pharmaceutical grade components for compounding drug products" and "[n]on-sterilized equipment . . . in sterile drug production,"[14] and issued a warning letter for "serious deficiencies in . . . practices for producing drug products intended or expected to be sterile, which put patients at risk."[15] FDA also recently took action against a compounding facility that sold "misbranded" weight loss products, including semaglutide, and manufactured products in insanitary conditions.[16] And, not long ago, a compounder in New England distributed injections contaminated with a fungus that led to over 60 deaths in 9 states[17]—a "tragic reminder of why compounding and compounded drugs can present serious risks to patients."[18]

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12 *See e.g.*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024

13 FDA, FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness (Nov. 1, 2024)

14 Form FDA 483 to N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding, 6 (Mar. 10, 2022), https://www.fda.gov/media/160771/download.

15 *E.g.*, Warning Letter from Div. of Pharma. Quality Op. II to J. Graves, Vice President, N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding (Nov. 18, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-american-custom-laboratories-llc-dba-farmakeio-superior-custom-compounding-642792-11182022.

16 FDA Warning Letter to ProRx, LLC, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prorx-llc-696742-12202024

17 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/december-13-2018-owner-and-four-former-employees-new-england-compounding-center-convicted-following.

18 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/december-13-2018-owner-and-four-former-employees-new-england-compounding-center-convicted-following

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In short, the risks from mass-produced compounded products are real and extremely serious. FDA has expressly warned compounders of these risks, stating that it had received "reports describing patients who experienced adverse events following the administration of compounded semaglutide."[19]

We urge you to apply the FBC Advertising Guidelines for prescription drugs to the Hims' advertisement to ensure that your rules are followed and your viewers are not misled or harmed.

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[19] Letter from S. Glueck, Pharm.D., FDA to P. Dickison, PhD, RN, Nat'l Council of State Bds. of Nursing (July 16, 2024), https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/nursing/fda-safety-alert.pdf.