



BY EMAIL

Dr. Catherine Gray
Director, Office of Prescription Drug Promotion
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

February 5, 2025

Re: Irresponsible Super Bowl Commercial by Hims & Hers Health

Dear Dr. Gray,

We write to express our alarm over a dangerous commercial for compounded semaglutide that Hims & Hers Health (Hims & Hers) plans to run during the Super Bowl on February 9.¹ The full 60-second commercial was recently posted on YouTube.² **As a knock-off copy of a prescription drug, the commercial for this product should comply with FDA prescription drug ad rules.** We request you act to enforce the laws and guidelines that protect Americans from misleading marketing in health products.

Already, public health experts have called the commercial “incredibly irresponsible.”³ We agree. The commercial is blatantly misleading, and poses a substantial risk of harming the approximately 200 million consumers that will see the commercial during Super Bowl LIX. And while this is likely the most egregious example of misleading advertising by compounders, recent academic research highlights that deception is commonplace among those who market compounded weight-loss drugs.⁴ American consumers deserve better, and we call on FDA to take swift action to prevent Hims & Hers from continuing to mislead the public through further dissemination of its commercial that should comply with prescription drug ad guidelines.

The commercial is misleading in its entirety, but we highlight three particularly egregious aspects of it:

¹ Katie Deighton, *Hims & Hers to Advertise Weight-Loss Shots at the Super Bowl*, THE WALL STREET JOURNAL (Jan. 28, 2025), <https://www.wsj.com/articles/hims-hers-to-advertise-weight-loss-shots-at-the-super-bowl-e0e92ce1>.

² *Hims & Hers Big Game Commercial: “Sick of the System,”* YOUTUBE, <https://youtu.be/I5i6QMNgoc>.

³ Katie Palmer, ‘Incredibly irresponsible’: Hims Super Bowl ad downplays risks of compounded drugs, STAT NEWS (Jan. 28, 2025), <https://www.statnews.com/2025/01/28/super-bowl-ad-hims-and-hers-telehealth-company-downplays-risks-compounded-drugs/>.

⁴ Ashwin K. Chetty et al., *Online Advertising of Compounded Glucagon-Like Peptide-1 Receptor Agonists*, JAMA HEALTH FORUM (Jan. 17, 2025), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225>.

- Hims & Hers heavily promotes and sells compounded semaglutide with “Hims” and “Hers” branding. As FDA itself has repeatedly explained, “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.”⁵ But no one would learn that from watching the commercial, because it omits that Hims & Hers’s semaglutide products are compounded drugs that have not been approved by FDA. Hims & Hers clearly understands that they need to explain these critical facts to consumers because they include a disclaimer. However, the disclaimer appears only briefly in tiny gray font at the bottom of the screen that is nearly imperceptible to an average viewer, without any accompanying audio disclosure.
- The commercial doesn’t just leave out that Hims & Hers’s products are compounded, unapproved, and riskier for patients, it discloses no risks whatsoever. Instead, the commercial just boasts that Hims & Hers offers “medications that work” and claims the unapproved semaglutide product achieves “life-changing weight loss” and will “feel great in your body.” FDA rightly requires anyone promoting FDA-approved drugs to provide “fair balance,” which requires doing much more than just touting benefits and ignoring the potential risks that accompany a prescription drug. Hims & Hers must—at a minimum—be held to the same standard as manufacturers of approved drugs when it promotes its decidedly riskier compounded products.
- The commercial claims that Hims & Hers drugs are “formulated in the USA.” But Hims & Hers did not “formulate” semaglutide. They simply offer knockoff versions of semaglutide—a drug that was formulated by Novo Nordisk following decades of research and billions in investment. Hims & Hers may be trying to suggest that its compounded semaglutide is “made in the USA” but there is no proof of that. Industry-wide, the components used to compound semaglutide are often sourced not from the United States but from foreign entities. The FDA has warned, both in general⁶ and specifically⁷, that compounders have violated the law by using ingredients from facilities that are unregistered, uninspected, or both.

Americans look to the FDA to ensure that they are not misled about prescription drugs which is why we have rules around such advertising in the first place. We strongly urge FDA to take action and stop Hims & Hers from misleading the 200 million people who will see this commercial if it runs during Super Bowl LIX.

⁵ *FDA’s Concerns with Unapproved GLP-1 Drugs Used for Weight Loss*, U.S. FOOD & DRUG ADMINISTRATION (Dec. 18, 2024), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss>.

⁶ *Ibid.*

⁷ FDA Warning Letter #696742 to ProRX, LLC, date December 20, 2024, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prorx-llc-696742-12202024>, accessed February 5, 2025



Respectfully,

Shabbir Imber Safdar, Executive Director

The Partnership for Safe Medicines

1300 I St, NW, Suite 400E

Washington DC 20005